Types of Procedures

Public supply, works and service contracts are awarded through one of three different types of procedures, namely: (i) an open procedure, (ii) a restricted procedure, (iii) a negotiated procedure and (iv) a "competitive dialogue" procedure. The open procedure has priority over the restricted procedure, the negotiated procedure and the "competitive dialogue" procedure.

Acting stricter than provided by the underlying EU directives, the restricted procedure generally ranks above a negotiated procedure. Only those contracting authorities which operate in the fields of drinking water, energy, transportation or telecommunications may freely choose from among the four procedures provided by the GWB.

Open Procedure

Open procedures are those procedures in which an unlimited number of undertakings are invited to submit a tender by public announcement. The rules on the time limit for the receipt of tenders are strict. The tenders may not be negotiated after their submission.

Restricted Procedure

Restricted procedures involve a public invitation to participate followed by a limited number of undertakings then being invited to submit a tender from among selected candidates. For the rest, the restricted procedures follow the same rules as the open procedures.

Negotiated Procedure

Negotiated procedures involve a public invitation to participate followed by a limited number of undertakings then being invited to submit a tender from among selected candidates. For the rest, the negotiated procedures are not regulated. Nevertheless the contracting authorities are obliged to follow the general principles as the "principle of competition," the "principle of transparency" and the "principle of non-discrimination" as laid down in Sec. 97 GWB.

Competitive Dialogue Procedure

The new "competitive dialogue" is an attractive alternative to the negotiated procedure for certain particularly complex projects with the objective of providing for a flexible procedure which preserves not only competition between economic operators but also the need for the contracting authorities to discuss all aspects of the contract with each candidate.

Individual Rights of the Tenderer and Legal Protection

One of the great achievements of the comprehensive 1998 amendment of the German law on public procurement was to establish basic legal rules to protect the individual rights of tenderers. This amendment was promulgated to harmonize German public procurement law with standards established in European law. The GWB provides that undertakings have a right to bring a claim to ensure that the provisions concerning award procedures are complied with by the contracting entity.

Structure of the Jurisdiction

Public procurement awards are subject to the review of Public Procurement Tribunals upon the application of a tenderer. These tribunals, which have been established both by the Federal Government as well as by State authorities, may also institute preliminary remedies if certain of the applicant's rights are jeopardized during the award procedure. Decisions of a Public Procurement Tribunal can be sent to the Court of Appeal which has jurisdiction over the relevant Public Procurement Tribunal.

Legal Remedies to get the Award

While the EU directives on public procurement do not prescribe any structure for legal remedies, the German public procurement law has developed an effective and detailed system of legal remedies in favor for applicants as also for tenderer.

Condition for each legal remedy is the previous complaint of the applicant or the tenderer. This complaint has to be filed to the contracting authority instantly after noticing the mistake in the tender documents or the misconduct of the contracting authority. “Instantly” means normally “within three days”. However if the applicant or tenderer needs legal advice in order to recognize the fault, the limit may be extended up to 14 days. If the applicant/tenderer fails to comply with this obligation to immediately file a formal complaint, he will be barred from filing a later complaint in respect to this alleged infringement.

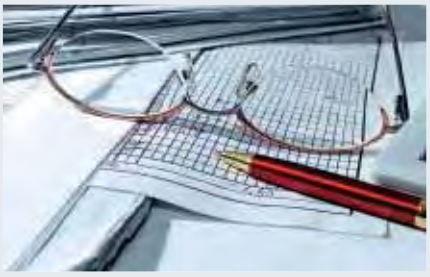
The contracting authority has to inform the unsuccessful tenderers about the outcome of the selection 14 days before giving the award to the tenderer with the best offer. The unsuccessful tenderers have to be informed about the name of the successful tenderer and the reasons why their tenders have not been selected. If the contracting authority does not inform the tenderers completely as prescribed or gives the award before the end of the 14 days period, any contract with the preferred tenderer would be void. The German jurisprudence has extended this provision in favor of the tenderers to state that any public contract concluded without any public procurement procedure is generally regarded as void.

The unsuccessful tenderer has to file his claim at latest within the period of the prior notice. Otherwise the contracting authority could terminate the procurement procedure by giving the award to the selected tenderer. This contract concluded after the 14-days-period could not be revoked by any later court decision. However, if the claim has been filed to the competent court the contracting authority may (with limited exceptions) not finalize the contract with its preferred bidder during court proceedings. Any legal transaction contrary to this prohibition is void.

Legal Remedies to Receive Compensation

If the contracting authority has accepted the tender and concluded the contract with the tenderer before the competitor has filed his or her complaint before the Public Procurement Tribunal, and this complaint was served on to the contracting authority, neither said tribunal nor the Court of Appeal can revoke the contract.

A tenderer may subsequently demand compensation in a second proceeding before a civil court for the costs of preparing its tender or of its participation to the extent the contracting entity violates a provision intended to protect undertakings, provided the applicant would have had a realistic chance of being awarded the contract. In case the tenderer can submit evidence that his tender was the most economically advantageous one and that the contracting authority would have been obligated to conclude a contract with him, the tenderer can demand compensation for the profit he would have earned upon acceptance of the tender.



Current Developments

Legislation

The German Government has decided to implement the EU directives in the "old" complex system of GWB, VgV and the existing three bylaws (VOB/A, VOL/A and VOF) as soon as possible in 2006. An all-embracing reform with the objective to reduce the complexity of the German public procurement law by unifying the provisions of the existing three bylaws to one single body of regulations has been postponed for the time being.

Privatization

The growing trend of privatization of public functions by selling public enterprises (esp. public transport companies and public utilities) or subcontracting public services to private companies (recently esp. planning, establishing and running public buildings for a long period) is reflected in numerous law suits of discriminated tenderers. The court decisions have changed deeply the previous patterns of privatization. According the EU directives and also the GWB, the topics of a "public contract" are the delivery of works, goods and services. The law does not refer to the sale of public enterprises. However, in case the public enterprises deliver works, goods or services to any contracting authority the deal can be governed by the public procurement law. In the leading case the contracting authority established an enterprise, award this enterprise with the municipal waste disposal and sold all shares of this enterprise to a private company directly afterwards. The Public Procurement Tribunal examined the case from an economic perspective and decided that the sale of the shares of this public enterprise had to be regarded as an award of a public contract.

For exception of the so called „in-house privilege" the Directive coordinating procedures for the award of public supply contracts and also the GWB are not applicable provided that the local authority exercises over the institution concerned (and to which it wishes to award a contract) a degree of control similar to that it exercises over its own departments and, at the same time, that institution carries out the essential part of its activities with the controlling local authority or authorities (ECJ, Case C-107/98 – Teckal). The participation however, even as a minority, of a private undertaking in the capital of a company in which the contacting public authority is also a participant excludes in any event the possibility of such afore-mentioned public control over the institution (ECJ, Case C-26/03 – Stadt Halle). It can be regarded as a rule that the sale of public enterprises is governed by the strict procurement laws when the deal is intended to avoid a regular public procurement procedure. As described above, unsuccessful or companies simply not properly informed by the public institution can claim that such a privatization is void and has to be done again. Furthermore, the privatization (esp. of public transport companies) could be regarded as an unlawful subsidy if the contracting authority has disregarded the public procurement laws. This is also important for the successful bidder as he could be forced to pay back the economic advantage of the transaction.

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Chapter 16

Securitisation

by Reinhard Willemsen

As a result of the new Basel II capital standards issued by the Basel Committee for Banking Supervision, the German banking sector has dramatically increased the prerequisites for corporate access to traditional loan financing, in particular with a view to small and mid-size enterprises ("SMEs" or "Mittelstand"). Funding costs have risen, since banks seek higher returns on a risk-adjusted basis. Thus, it has become essential for corporations doing business in Germany to have access to alternative ways of financing. One option is to directly tap the capital markets through an asset-backed securities structure. Doing so basically uses the company's cash flow to back the financing. Receivables or other assets are sold to an offshore special purpose vehicle ("SPV"), which in turn issues debt securities in the capital markets. The sold assets back the payments of principal and interest to the investors (asset-backed securities). The investment risk with respect to the issued securities is thereby separated from the overall risk of the relevant company, usually resulting in highly rated debt securities and thus, cheaper funding compared to conventional loan financing.

Current Market Situation

While the German securitisation market is, measured against the size of the overall economy, still comparatively small, the future outlook is for continual growth. Meanwhile, most of the major German banks provide for the securitisation of asset pools of their corporate customers by way of so called conduit structures (Asset-Backed Commercial Paper Programmes or ABCP-Programmes). The Purpose of these programmes is to combine assets of multiple corporations on the back of which high volumes of highly rated money market instruments (asset-backed commercial papers or ABCP) are issued to allow for cheaper funding. Despite some major uncertainties and challenges, the German asset backed commercial paper market continued to grow in 2005, further demonstrating the importance of this product as a vital source of funding. In 2005 the volume of the German ABCP market increased to EUR 66 billion from EUR 49 billion in 2004. While the German ABCP market in principle has the potential to become Europe's largest in light of approximately 30,000 SMEs which could use asset-backed securities and asset-backed commercial papers as an alternative way of financing, the majority of such SMEs still struggles with the complexities of certain legal, tax and accounting issues, which are, together with ways to address them, presented below.

Legal, Accounting and Tax Issues

While Germany is still lacking a specific law on securitisation unlike many other European countries, there are, of course, numerous legal, tax and accounting issues influencing securitisation.

Insolvency Risk

One of the major issues is the lack of a clear true sale definition in German insolvency law. Such definition is essential to clearly distinguish between a legal true sale of assets and a secured loan transaction, the latter being subject to substantial administrator fees in a possible insolvency. Also, the insolvency administrator and not the purchasing SPV would be entitled to collect the assets. Both factors lead to a higher risk for investors, having a negative impact on the rating and, accordingly, the costs of securitisation transactions.

In the past, German courts, when dealing with transfer of receivables in factoring transactions, applied certain tests to determine whether or not a true sale of assets was achieved. The decisive test is the so called obligor default risk test or safe cash test, basically checking whether or not the risk of an obligor's default is fully transferred to and remains with the purchaser of assets, i.e., the seller of the receivables is not under an obligation to make good any losses.

Typical elements jeopardising an insolvency proof true sale are buyback obligations, guarantees for defaulted assets and purchase price or servicing fee adjustments depending on the amount of defaults.Thus, it is in any event necessary to closely scrutinise a transaction to make sure that it will receive a high rating and, as the case may be, will pass the obligor default risk test applied by German courts.

Assignment Restrictions

Receivables sold in a securitisation transaction may be subject to contractually agreed assignment restrictions, prohibiting the assignment of a claim by a creditor to a third party. Such assignment restrictions are common in the German market and recognised under German contract law. However, notwithstanding any contractual assignment restriction, sec. 354a of the German Commercial Code (Handelsgesetzbuch, HGB) provides that a claim may be validly assigned if the claim arises from a commercial transaction between merchants. This advantage comes at a cost: the debtor stays entitled to discharge its obligation by payment to the seller, thereby exposing the purchasing SPV to the credit risk of the seller. Thus, a transaction that heavily relies on sec. 354a HGB will probably not be able to qualify for the highest rating categories, resulting in increased costs of funding. To avoid this outcome, it is advisable to update the underlying contractual documentation and expressively provide for creditor's right to transfer the relevant claims, e.g. by way of its standard business terms.

Set-Off Risks

When the seller of receivables becomes insolvent there is always a set-off risk, since debtors will usually try to set-off against claims of the seller that have already been sold and assigned to the SPV. In general, under sec. 387 of the German Civil Code (Bürgerliches Gesetzbuch, BGB), two persons may set-off claims against each other provided that the claims are of the same nature. In addition such set-off may also be exercised vis-à-vis an assignee. In such a case, a debtor will be entitled to set-off against claims already sold and assigned to the SPV under sec. 406 BGB, except where either (i) the debtor was aware of the assignment at the time when the debtor acquired the counter claim vis-à-vis the seller or (ii) the counter claim became due (a) after the debtor was aware of the assignment of the seller's claim and (b) after the seller's claim became due. In addition sec. 404 BGB provides that the debtor may raise all defenses that it possessed at the time when the claim was assigned against the assignee, i.e. the SPV. Also, the SPV must recognise payments by the debtor to the seller under sec. 407 BGB until the debtor becomes aware of the assignment, usually by the SPV's notification. While in general such set-off rights may be validly excluded by agreement, such clause may be invalid if contained in the standard business terms.

Data Protection

Data protection and privacy regulations in Germany restrict the exchange and transfer of personal data and data subject to specific duties of confidentiality and secrecy within the scope of securitisation transactions. Specific restrictions and requirements exist for the public sector and for branches such as the telecommunications and Internet, life and health insurance, and banking. Depending on the particular circumstances of each transaction, data protection and privacy regulations may require that the consent of the debtors be obtained or require the implementation of a trustee structure. Furthermore, the transfer of personal data to countries not belonging to the European Economic Area is subject to additional requirements. In relation to the German banking secrecy, in 2004 the Frankfurt Court of Appeal (Oberlandesgericht, OLG) ruled in a preliminary injunction that the assignment of consumer loan receivables violates the banking secrecy and is therefore void. The rating agencies' view, however, coincided with that of the lawyers and some decisions of regional courts (Landgerichte) indicated that the decision of OLG Frankfurt will not become prevailing case law in Germany. German data protection laws are discussed in more detail in the chapter about data protection.

Real Estate

Where real estate is involved as collateral for the securitised receivables, the current legal requirements for transfers of commonly used registered mortgages (Buchgrundschulden) have been another obstacle for the German securitisation market, since said mortgages had to be re-registered individually at the relevant local land register to achieve a proper transfer. This process is not only time consuming but also subject to certain fees. In September 2005, however, a refinance register has been introduced. It allows

for registration of receivables and mortgages, which are, by such registration subject to segregation in the insolvency of the seller. To enable the purchaser of the assets to enforce the mortgages, still a re-registration is required with the land register and it is unclear whether the purchaser or the seller's insolvency estate is liable for the costs thereof.

Lease Receivables

Also, the securitisation of lease receivables arising from residential or commercial real estate lease contracts is subject to certain legal obstacles under German law, in particular sec. 110 of the German Insolvency Act (Insolvenzordnung, InsO), pursuant to which the assignment of receivables owed by tenants will become void following the landlord's insolvency.

Receivables from finance leasing, however, may be securitised if the underlying goods are transferred to the purchaser of the lease receivables as well. If such transfer is omitted, the consequences will be as set out above.

Trade Tax Exemption for SPV

Under the Small Businesses Promotion Act (Kleinunternehmerförderungsgesetz), SPVs that are purchasing loan receivables from banks and fund the purchase price from the issuance of debt securities or taking of loans are exempted from trade tax. Currently there is no similar exemption with respect to SPVs involved in the securitisation of other asset classes, such as trade receivables. Accordingly, all purchasing SPV that form part of ABCP Programmes are located in offshore jurisdictions, to avoid taxation.

Value Added Tax

In Germany the servicing of the securitised receivables usually stays with the seller for the benefit of the purchasing SPV. Until 2004, however, it was unclear whether such servicing is subject to value added tax. To avoid taxation, various structural elements have been used. This issue has then been resolved by a letter of the German Ministry of Finance in June 2004 confirming that the servicing will not be subject to value added tax where it stays with the seller.

Under sec. 13 c German VAT Act (Umsatzsteuergesetz, UStG), there is a risk that the SPV will become secondarily liable for VAT owed and not paid by the originator with respect to the sold receivables. Said risk could be minimised subject to certain prerequisites, laid out in detail in a letter of the German Ministry of Finance of May 2004.

Off-Balance Sheet Accounting

The accounting treatment under German GAAP (HGB) is governed by a paper that had been issued by the German Institute of Accountants (IDW) in 2002 and has been amended in 2003 (HFA 8). The paper provides that a true sale for accounting purposes and an off-balance sheet treatment may only be achieved if not only the legal title to the relevant assets is transferred from the seller to the purchaser but also the entire credit risk. The paper in particular deals with credit enhancements and purchase price discounts. Basically, the credit enhancements and discounts should not materially exceed the market discount rate and the historical default ratio. Although the said paper neither constitutes a binding professional rule for accountants nor is determinative for legal purposes, its conclusions are by now generally applied for accounting purposes under HGB.

Under the International Financial Reporting Standards (IFRS), which became compulsory for stock exchange listed companies in 2006, yet no similar guideline exists but a draft IDW letter is due for publication and industry comments in the course of 2006. Currently, the prevailing view among German accountants is, that under the respective IFRS rules IAS 27, SIC 12 and IAS 39 derecognition of securitised assets has to be determined by assessing whether the seller of the assets or the investor has the rights to receive the cash-flows arising from these assets rather than relying on the legal transfer of the assets. Since in most securitisation structures not all but a material portion of the rights to receive the cash-flows are transferred, a detailed analysis of the sellers' so called "continuing involvement" is required to determine whether or not the structure is off-balance. For tax purposes, however, the HGB accounting rules but not the IFRS are decisive.

Outlook

The German deal pipeline still is robust and dominated by credit-insured transactions originated by SMEs. The abolishment of state guarantees (Gewährträgerhaftung) with respect to state owned banks (Landesbanken), which acted as liquidity providers to various Conduit Programmes, did not affect the ABCP market as expected, since programme sponsors were able to even compensate rating deteriorations of liquidity providers by innovative enhancement techniques. Moreover, the German KfW Banking Group, owned by the federal government (80 %) and the states (20 %), heavily promotes the True-Sale-Initiative (TSI), a platform for true sale securitisation and standardisation, involving all of the major German banks. The TSI is currently aimed at creating a secondary market for the financing of SMEs. It is anticipated that this will change in the future and will expand to include other asset types.

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Chapter 17

Environmental Law

by Stefan Hitter

Environmental law in Germany is not regulated by a single act. It much rather encompasses regulations and provisions in a large number of different laws which serve to protect the environment.

Environmental protection is one of the major goals that public authorities in Germany must follow. The term „environmental protection" includes all measures that safeguard the environment against harmful influences. Environmental protection encompasses nature protection, countryside conservation, water pollution control, emission control, radiation protection, waste prevention and disposal, control of chemical substances, soil protection and in principle (although not yet regulated by law) climate protection.

Different levels of environmental protection legislation exist including European Law, Federal Law and State Law. As legal basis Article 20a of the German Constitution (Grundgesetz, GG) lists environmental protection as a general state goal. Even though state goals only set forth objective obligations and do not grant directly enforceable rights to individuals, state goals nonetheless serve to focus the respective obligations of public authorities.

The following laws can be designated as the key national laws in the area of environmental protection: the Federal Emission Control Act (Bundesimmissionsschutzgesetz, BImSchG), the Federal Nature Protection Act (Bundesnaturschutzgesetz, BNatSchG), the Recycling Economy and Waste Act (Kreislaufwirtschafts- und Abfallgesetz, KrW-/AbfG), the Water Resources Act (Wasserhaushaltsgesetz, WHG), the Federal Soil Protection Act (Bundesbodenschutzgesetz, BBodSchG), the Federal Forest Law (Bundeswaldgesetz), the Plant Protection Act (Pflanzenschutzgesetz, PflSchG), the Federal Building Act (Baugesetzbuch, BauGB), the Gene Technology Act (Gentechnikgesetz, GenTG) and the Atomic Energy Law (Atomgesetz, AtG). Also worthy of mention are the Environmental Information Act (Umweltinformationsgesetz, UIG), which grants every individual free access to certain environmental information from a government agency, and the Environmental Impact Assessment Act (Gesetz über die Umweltverträglichkeitsprüfung, UVPG), which serves to monitor the environmental impact of certain industrial facilities at an early stage and in a comprehensive manner.

Nature Protection and Countryside

Conservation Law

Of particular importance for site-related protection of the environment is the framework legislation promulgated at federal level in the form of the Federal Nature Protection Act (Bundesnaturschutzgesetz, BNatSchG). The objective of this Act is to protect, care for and develop the natural environment and the landscape in built-up and non-built-up areas in such a way that the efficiency of the natural household, the usefulness of natural assets, the world of flora and fauna and the diversity, uniqueness and beauty of the natural environment and the landscape are sustainably preserved as man's natural foundation of existence and as a prerequisite for human recreation. Nature is thus not protected for its own sake but rather as a resource for human beings. The Act thus contains provisions on landscape planning protection, care and development measures in general and for certain categories requiring particular protection, species conservation, recreation in the natural environment and landscape and the involvement of citizens' action groups. The framework Act requires expansion by the nature conservation legislation of the individual German Federal State.

Environmental protection measures must be balanced against one another and against the requirements of the general public with respect to nature and countryside. In order to achieve this goal, the law establishes a set of principles that clarify its intent and offer a more precise definition of the law's scope. These principles serve as guidelines for planning but are also relevant for individual measures. The principles should at the same time not be followed systematically, but are much rather to be followed to the extent required, possible, and appropriate for application in each individual case after considering all prerequisites. The authorities must not only observe the goals of environmental protection but must also support said activity. The law also provides for general protection, conservation and development measures which apply to everyone. According thereto, the individual responsible for an encroachment on nature and the countryside is obligated to refrain from causing avoidable injuries as well as to provide compensation for unavoidable derogations insofar as is necessary to achieve the goals of nature protection and countryside conservation.

Encroachments in this sense are defined as changes to the appearance or use of land that could have a significant or sustainable negative effect on the efficiency of the balance of nature or on the countryside. The obligation to refrain or to compensate only exists for encroachments if other legal provisions require official authorization or similar permission for the encroachment. An encroachment may be prohibited if derogations are unavoidable or cannot be compensated to the extent required and nature protection concerns outweigh all other demands on nature and the countryside. With the exception of such passive protective measures that address changes to a current condition, the Federal Nature Protection Act also includes active measures by protecting specific sections of nature and the countryside that are deemed particularly worthy of preservation. Such measures could include, for example, the declaration of an area as a nature protection area, a national park or a countryside cultivation area. Such a declaration must be set forth in the form of an ordinance, a law or a decree (depending on state law) with legally binding effect. Any investments impacting on nature and countryside must observe the provisions of the Federal Nature Protection Act and the implementing provisions of the German States thereto. Little room for negotiation exists to the extent these laws are triggered by an investment.

The Federal Nature Conservation Act is complemented by the Federal Forestry Act (Bundeswaldgesetz) which also contains environmental law provisions as they relate to forests.

The legal basis of nature protection law can also be found in EU Community law which focuses on species protection but is developing more and more into a comprehensive biotope protection law. In particular the Directive 79/409/EWG on the conservation of natural habitats as well as of animals and plants in the wild (Fauna-Flora-Habitat Directive) provides for the establishment of a community-wide integrated biotope system for which purpose Member States are to set-aside land as specially protected areas. To the extent a project raises concerns that a protected area could suffer significant damage, Germany, as a Member State, must check compliance with the conservation targets established for said area. The Directive is of vital importance for investments in outlying areas not yet included in a zoning or another type of plan to the extent a project impacts upon protected areas.

Federal Soil Protection Act

The Federal Soil Protection Act (Bundesbodenschutzgesetz, BBodSchG) is of vital importance to real estate investments. The purpose of this Act is to protect or restore the functions of the soil on a permanent sustainable basis. These actions include prevention of harmful soil changes, rehabilitation of the soil, of contaminated sites and of waters contaminated by such sites and precautions against negative soil impacts.

To achieve this goal, detrimental changes in the soil, disruptions of its natural functions and of its function as an archive of natural and cultural history are to be prevented as far as possible. The soil and residual pollution must be decontaminated and cleaned-up, and measures implemented to prevent harmful effects on soil. The law has three objectives: damage prevention, decontamination and precautionary measures. The law applies to all detrimental changes to soil and to residual pollution to the extent that no standards are expressly designated which establish independent rules regarding the effects on soil. The Soil Protection Act furthermore prevails over contradicting State law.

The term “detrimental changes to the soil” is the principal codified criterion for the obligation to prevent damage. Changes that harm the soil impair the function of the soil and are sufficient to pose a threat to, have considerable disadvantages for or significant detrimental effects on individuals or the general public. An initial suspicion of danger is therefore sufficient. The danger need not actually have arisen, however, the possible disadvantages and harmful effects must be significant. Another key term contained in the Soil Protection Act is that of “residual pollution”. This term applies to all facilities which have been shut down as well as to other property on which hazardous materials and substances have been treated, stored or deposited as well as to land on which shut-down facilities exist and other property on which substances harmful to the environment have been handled (with the exception of plants pursuant to the Atomic Energy Law) if such installations had a detrimental effect on the soil or resulted in other dangers for individuals or for the general public. The law also includes the term “suspected site” that refers to land upon which harmful changes to the soil are suspected.

Obligations to Prevent Contamination

On the basis of the aforementioned key legal terms, every individual whose actions impact upon soil is obligated to avoid harmful changes thereto. This obligation begins with human behaviour that can be identified as having harmful effects. The obligation applies to everyone whose actions are likely to exceed the minimum limit of risk. The landowner and the person with actual control over the property are furthermore obligated to implement measures to prevent harmful changes to the soil on said property. This obligation is not connected to human behaviour, but rather to the condition of the property.

Obligations to Decontaminate

If a harmful change in the soil or residual pollution has already occurred, the polluter (and its successor), the landowner as well as the person with actual control over the property have the joint and several responsibility to decontaminate the soil and to clean up the pollution as well as any groundwater contamination caused by the detrimental change in the soil or residual pollution. Such decontamination and clean-up must occur such that no lasting hazard, significant disadvantage or considerable nuisance remains for individuals or for the general public. With regard to the term decontamination, measures are to be applied:

- To eliminate or reduce pollutants (decontamination measures)
- To prevent or reduce the spread of contaminants in the long term (safety measures) and
- To eliminate or reduce harmful changes in the physical, chemical or biological properties of the soil.

Addressees of the Obligation to Decontaminate

Pursuant to the Federal Soil Protection Act, those individuals required to decontaminate the soil include not only the polluter, the landowner and the individual who actually controls the property as has traditionally been the case in conformity with principles of police and regulatory law. The following individuals and/or entities might now also be obligated to take remedial action:

- The polluter's successor;
- The former owner of the property who has given up his or her ownership of the property or assigned same to a third party and who has knowledge (or lacks knowledge due to negligence) of the environmental pollution;
- An individual who for reasons of commercial law represents a legal entity/company that owns property where evidence of a harmful change to the soil or residual pollution exists to the extent said entity/company is not capable of undertaking clean-up measures for financial reasons.

These regulations present a significant expansion of the definition of persons required to undertake decontamination measures. Due to the fact that former owners can also be obligated to decontaminate, a type of "perpetual liability" result. Even though this liability can be excluded if the former owner purchased the property in good faith under the assumption that no harmful changes in the soil or residual pollution existed, such good faith depends on the circumstances in each individual case.

The Federal Soil Protection Act additionally includes a number of supplementary obligations and measures. An example thereof is the performance of cleanup checks or the preparation of a cleanup schedule by the party in charge of decontamination.

A recent court decision of the European Court of Justice has significantly influenced the interpretation of the Federal Soil Protection Act. According to the Court contaminated soil is regarded as waste and has to be decontaminated regardless if the soil is excavated or not. In former decisions of German courts soil was regarded as waste only after excavation and the strict rules of the Waste Act obliging the owner to decontaminate applied only to movable assets. Since the court decision has to be observed by German courts this could have a great economical impact on the obligation to renovate and decontaminate soil polluted areas.

Emission Control Law

Emission control is primarily addressed in the Federal Emission Control Law (Bundesimmissionsschutzgesetz, BImSchG) and by its affiliated implementation ordinances and numerous administrative provisions - in particular the Technical Instructions on Air Pollution Control (TA Luft) and the Technical Instructions on Noise Protection (TA Lärm). The Law is the central piece of legislation for technical environmental protection and the technical safety of installations. Its purpose is to protect people, animals, plants, the soil, water, the atmosphere as well as other physical assets from harmful environmental impacts - in particular air pollution and noise pollution. To a large extent, the expression "harmful effects on the environment" is synonymous with that of "harmful changes in the soil" within the meaning of the Federal Soil Protection Act and covers emissions which, depending on type, extent or duration, are likely to cause significant disadvantages or a considerable nuisance to the general public or a neighbourhood. Neighbourhood in the sense of the Emission Control Law has a wide meaning and covers everybody who could be impaired by the harmful effects.

The full scope of the law applies as soon as an installation generates emissions in the form of air pollution, noise, heat, vibrations and similar emissions described by the law. The law thus applies in cases involving emissions caused by an installation. This should not be confused with emissions caused by the conduct of an operator of an installation, which conduct is addressed by the police and regulatory laws of the respective Federal States.

Obligations of Operators of an Installation

With regard to the obligations of an installation's operators, a distinction must be made between those installations requiring a permit and those installations not requiring a permit.

To the extent installations requiring a permit ("installation licence") are involved, protection is extended to cover hazards and considerable disadvantages and nuisances caused in other manners as well as the prevention of harmful effects on the environment. Facilities within the meaning of the law include:

- permanent establishments and other stationary installations
- machines, devices and other movable technical equipment and
- property on which substances are stored or deposited or work is performed which could cause emissions (with the exception of public transportation routes).

Installations requiring a permit include operational facilities that are extremely likely to cause harmful effects to the environment or to cause considerable disadvantages or nuisances or to be a hazard to the general public or a neighbourhood as a result of their intended purpose of operation. Examples include production plants, energy facilities, and recycling machinery. Installations of this type are to be designed and operated so that no harmful effects to the environment or other hazards, significant disadvantages and considerable nuisances to the general public and a neighbourhood can result, so that harmful effects to the environment are prevented, and also so that waste is avoided to the extent possible. The installations furthermore must be erected, operated and shut down so that no hazards, considerable disadvantages, etc. to the general public and a neighbourhood can result even after the installations cease operation or the installation property is no longer used. Where the prerequisites are given, there is a legal obligation to grant the licence.

The Federal Emission Control Law also contains regulations on the procedure to be followed for granting a permit. These regulations are supplemented by special provisions or subsequent orders which address the revocation of a permit as well as the prohibition of, or closing down of an installation. Orders may in particular be passed retroactively after a permit has already been granted for the purpose of fulfilling obligations arising under the law. Governmental authorities are in fact obligated to issue such orders to the extent it is subsequently revealed that the general public or a neighbourhood is not sufficiently protected against harmful effects to the environment or other hazards. The authorities may even prohibit the operation of a facility under certain conditions, such as when the operator fails to satisfy a plausible, retroactive order regarding the purpose or the installation's operation. The authorities can also order an installation that was constructed, operated or significantly altered without the required authorization to be shut down or torn down. An installation can also be shut or torn down due to a lack of authorization where the authorities had previously revoked such authorization. The reasons for revocation comport with the general reasons for revocation as defined in the Administrative Procedures Act.

The obligations of operators of those installations not requiring a permit are regulated in detail by the Federal Emission Control Law. Said law provides that an operator is obligated to erect and operate the installation so that harmful effects to the environment are prevented, so that unavoidable harmful effects to the environment are kept to a minimum, and so that waste produced during the operation of the facility can be disposed of in an orderly manner. A number of legal provisions furthermore exist taking the form of legal ordinances which set forth in greater detail the requirements for installations not requiring a permit as well as the obligations of the operators thereof.

The competent authorities may issue orders in individual cases to insure that obligations of operators are fulfilled and that legal ordinances are followed. Should an operator fail to obey such a valid, official order, the authorities may prohibit further operation of the installation in full or in part until the order is satisfied. Operators are obligated through this sanction to meet Emission Control Law requirements. The authorities are furthermore required to prohibit the construction or the operation of an installation in full or in part if the harmful effects to the environment caused by the facility endanger the lives of, or are hazardous to, the health of people or valuable assets for as long as the general public or a neighbourhood cannot be offered sufficient alternate protection. The stated provisions also protect neighbours. This means that a neighbour affected by installation emissions can invoke this regulation before the authorities and demand intervention based on a violation of provisions within the context of the Federal Emission Control Law. The passing of regulatory orders falls under the discretion of the authorities, however, such that a neighbour only has a claim to obtain a decision free of discretionary errors. The situation is completely different in cases of neglect where the authorities are in fact obligated to intervene when factual requirements exist; a neighbour therefore always has to claim for official intervention in such a case.

Consequences of an Order or of a Prohibitive Order

Orders issued by a federal authority become effective upon notification of the operator. An order issued by a competent authority always relates to a specific installation; the order thus transfers and applies to the new operator in case an installation is subsequently sold. If an operator does not meet the obligations imposed, the government agency may employ “administrative coercion” against the operator, i.e., it is able to execute the order by means of coercion (in particular by imposing penalty payments) in accordance with the enforcement laws of the respective Federal States. An operator may make use of the standard remedies available under administrative law such as appeal or an action for rescission to contest agency orders.

Recycling Economy and Waste Act

The legislative intent behind the Recycling Economy and Waste Act (Kreislaufwirtschafts- und Abfallgesetz, KrW-/AbfG) is not only the disposal of waste in an environmentally compatible manner but also the promotion of a so-called recycling economy. This term primarily covers waste prevention, in particular through the internal recycling of substances at installations, product design which generates little waste and consumer behaviour oriented towards products that generate less waste and fewer pollutants. Recycling economy and waste law is codified in the Recycling Economy and Waste Act, which is heavily influenced by European Community law and has implemented numerous EU Directives. Provisions relevant to waste law are also included in innumerable other laws, for example in the Federal Mining Law, the Law on the Transportation of Hazardous Goods, the Atomic Energy Law, as well as in the Water Resources Act, which laws regulate specific waste problems within the scope of their application such that they do not fall under the Recycling Economy and Waste Act.

Obligations of the Responsible Persons

According to the recycling economy principles contained in the Act, residues are to be avoided in particular through a reduction in quantity and degree of harmfulness, while recycled material is either to be reused or applied to generate energy. Material recycling covers the substitution of raw materials by materials recovered from waste or by the use of the material properties of waste for primary or secondary purposes, excluding direct energy recovery. The law distinguishes between four different categories of waste, all of which have various requirements as to the manner in which the waste should be recycled or disposed of. Those who produce or are in possession of waste are required to recycle the waste as far as is technically possible and economically feasible. This priority of recycling over disposal is nullified if disposal offers the most environmentally compatible solution. Particular attention should be paid in such cases to the following:

- The expected emissions
- The goal of using natural resources sparingly
- The amount of energy used or generated
- The increase in the amount of harmful substances in recyclable waste or products generated by recycling waste

An obligation to dispose of waste exists for those residues that cannot be recycled. The disposal must permanently exclude such waste from the recycling economy. Disposal is defined as the provision, transfer, collection, transportation, treatment, storage and deposit of waste for disposal. Such disposal must take place to avoid impairment of the common good. Impairment exists in particular if:

- The health of individuals is impaired
- Animals and plants are endangered
- Water and soil are contaminated
- The environment is harmed through air pollution or through noise
- The concerns of spatial and regional planning, of nature protection and countryside cultivation as well as of urban development are not taken into account
- Public safety and order are threatened or disturbed in any other manner

Waste producers may be required to provide their waste to those entities legally responsible for waste disposal under respectively applicable State law (i.e., public law waste disposers) if unable to recycle or otherwise dispose of the said waste either by themselves or through a third party. In such a case, the owners and possessors of property on which such waste (which is to be processed) is generated are obligated to allow storage facilities to be constructed on the property to collect the residues and to allow public law waste disposers to enter onto the property to collect waste and monitor separation and recycling.

Water Protection

The guideline legislation in the field of water protection is the Water Resources Act (Wasserhaushaltsgesetz, WHG). In order to regulate water quality and water levels, water bodies are considered an integral part of the water balance and should be managed in such a way that they serve both the common good and, in harmony with this, the use to which individuals put them and that no avoidable damage to its ecological functions takes place. Everyone is obliged, taking account of particular circumstances, to exercise adequate care when carrying out measures which may have an impact on a water body so that water pollution or any other negative effect on the water is prevented; moreover, everyone is obliged to use water sparingly in line with the needs of the water household as a whole. Surface waters and groundwater are, as public utilities, subject to an extraordinary public management and utilisation code which leaves the allocation of users' rights at official discretion.

The Water Resources Act establishes the obligation of an installation's owner to pay damages regardless of fault if, under certain conditions, substances are released from the installation into a body of water resulting in harm to third parties.

Additional Branches of Environmental Law

Numerous other laws can be designated as environmental protection laws including spatial and regional planning set forth principally in the Spatial Planning Act, atomic energy and radiation protection provisions in the Atomic Energy Law, gene technology regulation in the Gene Technology Act, and hazardous materials law set forth above all in the Toxic Substances Control Act. Some of these Acts include special regulations for certain areas of environmental law (such as the Water Resources Act and the Gene Technology Act) or take environmental protection into account in addition to their primary legislative intent (such as, for example, the Spatial Planning Act, which codifies, among others, the need to protect, conserve and develop nature and the countryside including water and forests as a principle of spatial planning). The structure of these Acts is comparable to the laws described in more detail above and contains special regulations on authorization requirements and possible liability. Like the Water Resources Act also the Gene Technology Act and the Atomic Energy Law establish the obligation of an installation's owner to pay damages regardless of fault.

Apart from the above described public environmental laws, also parts of private and criminal laws protect individual citizens against the pollution of the environment.

The legal basis of private environmental laws is in part set forth in the German Civil Code (Bürgerliches Gesetzbuch, BGB). Of greater significance, however, is the Environmental Liability Law (Umwelthaftungsgesetz, UmweltHG) that establishes strict liability for polluters. The owner of a facility as defined in the schedules to said law is liable for damages incurred by another party hereunder if said party suffered damages as a result of the facility's impact on the environment either in the form of personal injury or property damage. Liability is capped at EUR 85 million.

Criminal environmental law is regulated in the Criminal Code (Strafgesetzbuch, StGB). Respective provisions contain criminal sanctions for the pollution of or encroachment on water, land or air.

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Chapter 18

Legal Aspects of Certain Industries

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Telecommunications

The German telecommunications market opened to competition on January 1, 1998. A rapid rush of new entrants to the market during the first years of open competition with more then 525 licencees and a total of more than 2,200 registered companies offering telecommunications services has been followed by a period of consolidation and concentration within the market. Despite the global difficulties that the telecommunications industry is facing at this time a vital market of local, national and international carriers and service providers has been established. Whereas the former monopolist Deutsche Telekom AG is still the most prominent player within this market, competitors' shares of all fixed line called minutes already totaled about 53 per cent by the end of 2005. This chapter will provide a brief overview of those legal aspects that must be considered if a telecommunications company intends to enter the German market.

Legal Framework

The legal framework for telecommunications is mainly set out in the Telecommunications Act of 2004 (Telekommunikationsgesetz, TKG). Whereas the German Parliament in 2005 adopted some crucial changes to the TKG the changes have failed to come into force until the end of the legislative period in 2005. Thus, the new German Government will now introduce another law to the parliament in order to change the TKG. As of April 2006, only governmental drafts of such new laws have become known to the public and it may not be foreseen what the outcome of the legislative process will be. Yet, three issues are likely to be part of the new legislation: First, Deutsche Telekom AG has built a strong position to ease regulations on it pertaining to the competitors' free infrastructure access in order to facilitate the remuneration of investments in new broadband infrastructure. Second, the legislator announced further improvement of consumer protection rules against value added services. Finally, national and European regulators both agree that the alleged lack of competition within the market of mobile telecommunications services will require a regulation of the four incumbent providers, particularly with regard to their pricing policies.

The Telecommunications market is regulated by an independent agency, the Federal Network Agency for Electricity, Gas, Telecommunications, Post and Railway (Bundesnetzagentur für Elektrizität, Gas, Telekommunikation, Post und Eisenbahnen, Federal Network Agency). Though, the Federal Network Agency is restricted to the regulation of "specified markets" where remarkable lack of sustainable competition has been identified. While the European Commission had issued a recommendation with particular markets that are likely to be regulated the Federal Network Agency has yet to complete national transformation of this recommendation as to the scope of regulated markets. Only upon such transformation, the Federal Network Agency will have to scrutinize said identified markets as to their competitive status.

Market Access

Providing of telecommunications services does not require the granting of a licence. Yet, all operators planning to provide any kind of electronic communication services for the public must register their names and services with the Federal Network Agency immediately after launching these services. Moreover, the use of the radio spectrum, e.g., for mobile communications services, still requires an application for the granting of respective frequencies.

It should be noted that all public carriers and providers for the public are subject to a mandatory financial contribution. The individual contribution amount will be calculated according to the operator's transaction volume and will be raised annually.

Interconnection

The TKG establishes the obligation of the incumbents (i.e. Deutsche Telekom AG) to interconnect their network with those of other carriers. Other carriers may be ordered to interconnect or give access as well if the Federal Network Agency deems this necessary for the providing of end-to-end services. The Federal Network Agency nevertheless established basic requirements that must be met by the requesting carrier before interconnection rights can be exercised, e.g. only a carrier with a minimum infrastructure (one switch and at least three transmission lines) will be entitled to interconnection.

If the incumbent does not grant interconnection or if the parties could not agree on the conditions for interconnection, the alternative carrier can appeal to the Federal Network Agency to issue an interconnection order.

Once the network of a carrier is interconnected with the network of Deutsche Telekom AG or any other carrier enjoying significant market power on its market, the carrier's customers have the possibility of accessing the carrier's network either on a call-by-call basis by dialing a short prefix (which is granted by the Federal Network Agency) or by being pre-selected as a default carrier. Yet, the TKG asks for a nearby feeding of incoming traffic from carriers that are selected by end users. Finally, mobile communications networks are exempted from the described selection obligation as long as they are subject to sustainable competition. According to a decision of the Federal Network Agency, Deutsche Telekom AG has been required to invoice and collect the fees earned by such carriers for connections on a call-by-call basis and to remit the respective fees to the carrier. Such an invoicing and collecting obligation has now become part of the statutory imposed duties for a carrier with significant market power.

Pricing

Rates and rate-related areas of standard terms and conditions of service of all operators with significant market power are subject to an ex-ante authority's approval solely when this fee is based on services that are deemed as being essential for the providing of an operator's services. Any other fee might only be subject to an ex-post control by the Federal Network Agency. This means that even certain fees of a carrier with significant market power might not be subject to an ex-ante approval. In terms of criteria for correct fees, the cost of efficiently providing the service is the most prominent criteria upon which fees are to be measured. Fees that are not cost-oriented might be seen as unfair and abusive, whereas the carriers are free to rebut this presumption.

On the other hand, fees for end-user services as well as access fees are not purely to be based on the cost of efficient service provision but they have to take such cost in consideration as one of a bundle of criteria. Yet, for the regulation of such end-user fees the cost of providing the service represents the maximum level the prices may not exceed. On the minimum side, prices may not be calculated as being dumping prices.

Under the regime of the 1996 TKG a new pricing method called "element based charging" had been introduced by the Federal Network Agency with effect as of January 1, 2002. Based on this method, a carrier must only pay for those parts of the Deutsche Telekom AG network actually used.

Moreover it should be noted that prices of interconnected carriers might not necessarily be completely equivalent. This means that for example non-incumbent local carriers are free to charge the interconnected incumbent carrier higher prices than the incumbents does regarding its own services. The Federal Network Agency explicitly acknowledged that different carriers may have different cost levels and therefore may be forced to charge higher prices in order to equalize their own costs.

Finally, the Federal Network Agency announced to be willing to start regulation of pricing within the market of mobile services in the next future. The Agency is particularly scrutinizing the monopoly position that each carrier holds within his own mobile network. While the Agency informed the public about its intention to implement an ex-ante regulation of pricing for mobile services such regulations have not yet come into force.

Access to the Local Loop and Other Network Elements

Unbundled access to the local loop is also governed by the TKG. Pursuant thereto, the incumbent carrier must provide unbundled access to the local loop and all other network elements.

Yet, competition for local calls could only develop when the providing of call-by-call services became available in mid 2003. Since then providers are free to provide local services either on a preselection or on a call-by-call basis. Though, in order to qualify for the required access to the Deutsche Telekom AG owned local subscriber lines on a national basis, the provider has to realize at least 475 interconnection points (Pol) with the Deutsche Telekom AG's national network whereas such a number of Pol is not necessary if the provider only seeks access in single location areas. At the end of 2004, service providers were able to provide a total volume of 15.2 billion minutes which equals 60 per cent of the entire volume of local calls provided by competitor's of the former incumbent while local carriers could add another 10.1 billion or 40 per cent of competitors' market share. While the incumbent, Deutsche Telekom AG, still remains the dominant provider of local calls the competitors' market share did significantly increase from 18 per cent in 2003 to ca. 33 per cent in 2004. It is worth noticing, that the Federal Network Agency may order any carrier enjoying significant market power to give unbundled access to certain network elements. This includes the providing of services to end users for resale as well as fee collecting and invoicing services towards end users.

Customer Protection

Consumer rights regarding telecommunications are now basically governed by the TKG whereas before July 2004 there had been partially a respective Customer Protection Ordinance that has been suspended in the wake of the TKG's 2004 revision. According to these rules, the customer has the right to demand an invoice listing each single telephone call. Moreover, the customer may request that only a single invoice be prepared by his or her local carrier even if several carriers were used on a call-by-call basis during the respective invoice period.

Moreover, any carrier of publicly available networks has to guarantee that users may transfer their respective extensions towards any other carrier as long as it remains within the same local num bering area.

Data Protection

Data protection for telecommunication services is mainly governed by the TKG and the general Data Protection Laws. Therein, the TKG provides that telecommunications operators may store and process any collected data relating to users by means of their own use even without explicit consent of such users in advance. It is the user's obligation to give notice of his disagreement in order to stop further storage and processing of data relating to his person. Though, concerning the transfer of any data relating to users towards third parties, an opt-in process is being installed meaning such transfer is only allowed upon the user's consent.

The same opt-in and opt-out regulations apply to traffic data collected by communications operators. Storage and procession for own use asks for the user's opting out, whereas transfer towards third parties requires the user's prior consent.

Concerning location data, the TKG requires the user's prior consent to the storage and processing of such data. Nevertheless, it is not necessary that such consent has to be asked for prior to every single use of a communications service. Whereas, the law leaves it to be sufficient if such consent was declared within the course of a general or framework agreement between the user and the communications operator.

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Health Sciences and Pharma

The health market covers many different areas determined by a variety of different legal provisions such as health law, including those of medical law, physician law, statutory health insurance law, pharmaceutical law and medical devices law as well as hospital law and the regulations of the federal law on epidemics. Due to the tight economic situation and the problematic revenue and spending trend in the statutory health insurance the health market is subject of substantial and frequent changes in the legal and political environment. These changes lead to a liberalization of the co-operation between physicians, hospitals and the health industry on the one hand but also restrict the economic possibilities in activities on the health sector. However, the health sciences industry especially the pharmaceuticals industry and the field of medical technology is still of particular interest to investors, as it is even now an especially lucrative industry, with much future potential. It is also an especially competitive market, and is likely to keep growing.

The sale of medicinal products and medical devices is regulated by strict laws that are mainly influenced by European directives and serve primarily to protect the health of patients and consumers. The law on medicinal products and medical devices sets out detailed regulations for everything from production to registration and sale, including the supervision of such sale and the import and export of the products. The following legal overview therefore focuses on the marketing of medicinal products and medical devices in Germany.

Compulsory Authorization of Medicinal Products

In Germany, as in the EU as a whole, ready-prepared medicinal products must be authorized; these are products that have been manufactured and packaged for the consumer before being placed on the market. Magisterial medicinal products do not have to be authorized. A ready-prepared medicinal product may only be placed on the market in Germany once a pharmaceutical business has acquired a permit to do so. Authorization under the law on medicinal products is the legal prerequisite for this permit. Exceptions to the rule include, for example, medicinal products destined for human clinical trial. Homeopathic pharmaceuticals do not require a compulsory authorization but have to be registered with the respective federal authority.

Prior to the authorization a medicinal product may only be provided to patients if they suffer from a serious or life-threatening disease which cannot be treated with an already authorized medicinal product (compassionate use).

Conditions of Authorization

The pharmaceutical entrepreneur, i.e. the party placing the drug on the market under its name, has to apply for authorization. This party must have its seat in a member state of the EU. For medicinal products for human use, applications have to be filed with the Federal Institute for Medicinal and Medical Products (Bundesinstitut für Arzneimittel und Medizinprodukte – BfArM) respectively the Paul Ehrlich Institute (PEI) as Federal Agency for Sera and Vaccines. Information in German on the usage, effect, dosage etc. of the medicinal product has to be submitted with the application. The results of analytical, pharmacotoxicological tests and clinical trials must also be presented. Regarding the latter two tests, it is in certain cases not necessarily carrying out tests of its own, but referring to available scientific research material instead.

This happens if:

- The effects of the medicinal product have been established and are apparent from scientific research material (known as "well established use" procedure)
- The medicinal product, in its combination of constituents, is comparable to a known medicinal product (known as the "essentially similar" procedure)
- The medicinal product is a new combination of known constituents. In this case, the reference is valid for these constituents

In cases where a medicinal product is registered by referring to established information, the interests of the party who originally registered the drug have to be taken into account. This is commonly a large pharmaceutical company carrying out research, which perceives making reference to the documentation on the pharmatoxicological tests and clinical trials for one of its products for the purpose of registering imitations as an infringement of its proprietary rights. Hence, the law on medicinal products stipulates a ten-year period of protection for documentation on new medicinal products. This gives the original applicant sufficient time to reap the financial rewards of its authorization for the medicinal product concerned before the subsequent applicant may enter the market with reference on the same documentation. In accordance with the objective of this law, only documentation on innovative developments is protected. The ten-year protection period starts from the time a medicinal product is first registered in a member state of the EU. It is therefore possible that, when a new medicinal product is first registered in Germany, the protection period might have expired because the drug has already been registered in another EU member state for more than ten years. The exploitation of documentation protected under this law may only be made with the written permission of the party who first registered the drug.

The authorities have to decide on an application for registration within seven months; this period is often extended when the applicant is given the opportunity to provide missing information or rectify formal errors in the application. In practice, the authorities generally take much longer than seven months to reach a decision as the number of applications exceeds their capacity. This is a disadvantage for applicants, as it delays the launch of the medicinal product concerned. Suing for damages is unlikely to be successful, as proving negligent conduct on the part of the authorities is difficult.

Granting Authorization

When a medicinal product is authorized, an authorization number is assigned to it. Different pharmaceutical forms of the same medicinal product or different concentrations of a medicinal product in the same pharmaceutical form are all issued with the same authorization number. A medicinal product may only be placed on the market after receipt of confirmation of its authorization. It is possible to appeal against an authorization granted with restrictions or against the refusal of a registration, and then to take legal action. The pharmaceutical entrepreneur is liable for a medicinal product he places on the market under civil and criminal laws, regardless of the product's authorization.

European Admission Procedures

Besides the admission procedure with the national authorities of each member state of the European Union there exist two procedures for authorizing medicinal products in Europe, i.e. the mutual recognition procedure and a centralized admission procedure.

The "mutual recognition" procedure is applicable to the majority of conventional medicinal products and offers the possibility of a simplified procedure to apply for a marketing authorization in different member states if there is already an approval of another member state. The holder of a marketing authorization issued by a member state for this purpose has to inform the reference member state that an application is to be made in accordance with the mutual recognition procedure and request the preparation of an assessment report. The reference member state shall prepare such assessment report within 90 days of the receipt of the request. In addition the holder of the initial marketing authorization has to submit an application to the competent authorities of the additional member state and has to testify that the dossier is identical to the one previously accepted or whether there are any additions or amendments to be made. According to the mutual recognition procedure the additional member state has to recognize the marketing authorization within 90 days of receipt of the application and the assessment report.

Certain biotechnological or innovative medicinal products have to be assessed by a centralized procedure with the European Agency for the Evaluation of Medicinal Products (EMEA). Medicinal products that have been approved within such a procedure are issued a marketing authorization that is valid throughout the EU. Furthermore the EMEA is responsible for applications with regard to the development of medicinal products for rare diseases, so called "orphan" drugs. These are products for the diagnosis, prevention or treatment of life-threatening or very serious conditions that are rare and affect not more than 5 in 10,000 persons in the European Union. To promote the development of such orphan medicinal products the European Union provides incentives, which are market exclusivity for ten years, the provision of scientific advice by the EMEA, the access to the centralized admission procedure and the granting of reduced fees e.g. regarding the application for marketing authorization.

Renewal of Authorization

Authorization does not automatically confer the right to market a medicinal product for an unlimited period. By law, the conditions under which a medicinal product has been put on the market must be reviewed every five years. The party concerned has to apply to renew the authorization three to six months before it expires. A report on whether the assessment criteria for the medicinal product have changed in the previous five years has to be submitted. Authorization lapses if the holder of the authorization fails to apply for renewal or forgoes the authorization in writing. In either of these scenarios, the medicinal product may continue to be sold for a period of two years after the lapse in authorization.

Sale of Medicinal Products

Unlike other products, such as groceries, medicinal products must not be made freely available to consumers in unlimited amounts. Their sale requires particular competence, and should be connected with specialist advice. By law, only qualified persons and establishments may sell medicinal products. The law also specifies the channels through which different categories of medicinal products may be sold, and sets out the conditions under which they may be passed to patients. A medicinal product's risk category can make a considerable difference. For example, a medicinal product can be sold freely, i.e. in a pharmacy or elsewhere, be limited to sale through pharmacies, be subject to prescription or even be subject to special permits and supervision under the law on anesthetics.

Since January 1, 2004 it is now possible for a pharmacy to distribute medicinal products via mail order if the competent authority grants permission. This also applies to the distribution via electronic commerce. However, to ensure the safety of the patients the mail order distribution is only allowed under strict requirements. Therefore, the mail-order pharmacy has to prove its quality and reliability, the customers have to be provided with a qualified pharmacological and medical advice and the delivery has to be carried out in a fast and safe way.

The pharmaceutical entrepreneur, generally a pharmaceutical company, places the medicinal product on the market under its name and has full liability for it. Its name must be displayed on the medicinal product's packaging, package leaflets or inserts and information material on the product. Granting another company co-distribution rights is also possible. If this is done, the holder of the authorization must inform the authorities that another company is also making use of the authorization and distributing the medicinal product concerned under its name. The co-distributor does not acquire any rights to the registration, and may only distribute the product in the form permitted by the authorization.

Import of Medicinal Products

Safety considerations and the unbiased treatment of domestic and imported medicinal products result in the import of medicinal products being possible only under certain conditions. Under the law on medicinal products, imports from EU member states are treated as domestic products, while the import of medicinal products from other countries is subject to additional conditions. When applying for German authorization for a medicinal product manufactured abroad, proof that the manufacturer is permitted to manufacture medicinal products under the laws of its country must be presented. The permit granting the right to place the medicinal product on the market in the land of manufacture also has to be submitted. To import ready-prepared medicinal products from a non-EU or non-EEA country, an import permit from the relevant authority has to be produced. In certain exceptional cases conclusively listed in the law, no import restrictions apply. The lack of restrictions in these cases serves the interests of travel and trade as well as good diplomatic, bureaucratic and scientific contacts. Medicinal products freed from import restrictions include those carried as part of personal travel needs or those required by a pharmaceutical entrepreneur as samples or for the purposes of analytical comparison.

Medicinal products ordered by pharmacies in precisely defined circumstances are also free from import restrictions, on condition that only small amounts of the products are specially ordered by individuals from a pharmacy. Doctors ordering medicinal products for the needs of their practices count among these individuals. Apart from this, the medicinal products must also be approved for sale in their land of origin and be passed to the individual in the course of a pharmacy's normal business, i.e. the products may only be handed over on the pharmacy's premises or delivered by post or courier. Stockpiling a supply at pharmacies by means of such special orders is not permitted. In the case of medicinal products from non-EU or non-EEA countries, a doctor's prescription is also required.

Medical Devices

Besides Pharmaceuticals the market for Medical Devices shows a significant growth and especially medical technology innovations have been significantly accelerating.

Medical Devices are also subject to extensive legal requirements determined by the Medical Devices Act (Medizinproduktegesetz, MPG) based on various European Directives. According to these directives medical devices are defined as any instrument, apparatus, appliance, material and pertinent software, or other article intended for human use in the diagnosis, prevention, monitoring, treatment and alleviation of diseases or as compensation for an injury or handicap. The term applies to any device used for the investigation, replacement or modification of the anatomy. Also included are physiological processes, including contraception testing, as well as in-vitro diagnostics which may be carried out in a laboratory or at home. Unlike Pharmaceuticals Medical Devices are not subject to an official authorization but the manufacturer is responsible for the conformity of the products with the essential requirements for medical devices in the applicable classification.

With the exception of some medical devices, such as custom-made devices or devices intended for clinical investigations or in-vitro-diagnostics, medical devices may only be placed on the market or put into service if they bear a CE marking, which establishes that the manufacturer's product conforms to all applicable legal requirements. This has to be proven in a conformity assessment procedure to ensure the safety the therapeutic or diagnostic benefit, the clinical or diagnostic evaluation of the medical device and the monitoring of the medical device and its manufacturer. Medical devices are classified in four risk potential classes. Depending on the product's risk level, a conformity assessment procedure has to be carried out and, if the device has not only a low risk level of a Class I medical device, a Notified Body must be employed. The Notified Body's identification number accompanies the CE marking. Once a Medical Device has passed the conformity assessment procedure in a member state of the EU the marketing and commercializing is allowed throughout the European Economic Area.

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Plant Variety Rights

Plant innovations, in particular new plant varieties, may be protected in Germany by applying for a Plant Variety Right (Sortenschutzrecht, hereinafter referred to as "PVR"). Although a national legal system of protecting plant innovations through the granting of PVR exists, it seems advisable to seek protection for plant innovations on a European level. The Council Regulation on Community Plant Variety Rights ("CPVR") established a uniform protection system for new varieties in the entire territory of the community.

Under the applicable regulation, varieties of all botanical genera and species, including, inter alia, hybrids between genera or species, may form the object of a CPVR.

Entitlement to and Application for a CPVR

The person who bred, or discovered and developed the variety or his successor in title, shall be entitled to the CPVR. The application for a CPVR may be filed at the Community Plant Variety Office ("CPVO") by the breeder or his successor or through a representative. The application must be accompanied by a detailed description of the supposedly new variety and contain a denomination.

Examination of the Application – Granting of CPVR

The CPVO will conduct a formal, a substantive and a technical examination. The last and most important examination mainly consists of the so-called DUS Test, i.e. the test whether or not the variety is Distinct, Uniform and Stable. These essential conditions must be fulfilled by any plant innovation to qualify for a CPVR.

Costs for the Application

A number of individual fees will be charged by the CPVO during the process of examining the application for a CPVR. An application fee of € 900 applies. Depending on the species, the costs for the technical examination range from € 1,020 to € 1,200. Upon the granting of a CPVR an annual fee of now € 200 applies.

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Broadcasting Law

Definition of Broadcasting

From a German law perspective the term "Broadcasting" covers all kind of television and radio services. "Broadcasting" in general is defined as follows: "Broadcasting is the provision and transmission for the general public of presentations of all kinds of speech, sound and picture, using electromagnetic oscillations without junction lines or along or by means of a conductor."

This definition includes presentations transmitted in encoded form or receivable for a special payment, as well as videotext. As a matter of fact all kinds of providing radio and television services fall within the meaning of "Broadcasting," no matter if such transmission is analogue or digital or is made by terrestrial devices, via satellite or through cable networks.

Sources of Law

The German Constitution guarantees the freedom of broadcasting. Further, the Constitution stipulates that sole responsibility for broadcasting rests with the Federal States as part of their "cultural sovereignty." Thus, the Federal States were entitled and obliged to create a legal framework that complies with constitutional law. Due to fact that the Constitution contains rudimental statements concerning broadcasting issues, the jurisdiction of the German Federal Constitutional Court had to clarify constitutional demands on the creation of a broadcasting system. Therefore, the Federal Constitutional Court made a series of decisions, which are especially known as "broadcasting judgments."

With the advent of cable and satellite, all Federal States drafted media laws in the 1980s. These laws specifically regulate the electronic media outside the conventional public corporations, mainly by granting commercial radio and television licences and deciding what programs may be fed into cable networks. For this purpose media regulatory authorities were created. A national framework of regulations is laid down in a treaty between all Federal States. In addition, 15 different media laws and media authorities exist, almost one in each Federal State.

Dual Broadcasting System

Beginning in the early 80s each Federal State decided for implementing a "dual broadcasting system." This means, that private broadcasters were able to provide their services alongside the public-broadcasting corporations since then.

The public service broadcaster is an independent and non-commercial organization, financed primarily by audience fees. The typical public service broadcasting organization provides a region, usually a Federal State, with public service radio and television (such as WDR in North Rhine-Westphalia or BR in Bavaria). All regional corporations joined together to found the ARD ("Arbeitsgemeinschaften der Rundfunkanstalten Deutschlands") and contribute to the first TV channel according to their size. The Second German Television ZDF (Zweites Deutsches Fernsehen) is based on a treaty of all Federal States (ZDF-Staatsvertrag). Both ARD and ZDF are active in digital television. ARD and ZDF offer a whole range of freely accessible digital channels. They are also involved in different projects to test and develop distribution via the Internet.

However, also private competition started to challenge the public system. Two commercial television channels started operation, one from Luxembourg (RTL), and the other as part of a cable pilot project in Ludwigshafen (Sat1). Meanwhile, a huge range of full service and special interests channels are licenced and distributed as analog and digital Free-TV. Mainly those channels are broadcasted by companies which belong either to the RTL- or the ProSieben-Sat1-Group. Nevertheless, an increasing amount of independent broadcasters has started to provide new offers.

As mentioned above, television services in Germany have to comply with the regulations of the treaty between all Federal States and the particular media laws. In any case in Germany a licence (concession) from a media authority or a comparable foreign authority is required for broadcasting television services. Due to the small capacity of analogue cable networks it is easier to apply for a satellite licence. With relation to analogue cable distribution a licence sometimes can only be applied for if the media authority has put licenses out to tender.

The private service has to observe the existing broadcasting regulations as prescriptions for licensing, financing, advertising, youth protection, or ownership regulation. Any applicant or licence holder has to comply with several personal and material provisions.
The treaty between the Federal States also contains rules for digital television. In short, the legal framework makes it easier to apply for a licence to provide a digital service and further gives more freedom of decision to network operators concerning the selection of programs to be distributed.

Nevertheless, due to the ongoing importance of analogue television transmission via cable networks such distribution is still economically essential for private television services. According to German broadcasting law mainly media law or the responsible media authority decides whether a channel has to be distributed in an analogue cable network or not. Since a few years several media laws started to grant more freedom of decision to cable network operators also concerning analogue distribution. Anyway, a diligent network management and a consistent network protection against or with media authorities and network operators remain essential for a program's chance to reach its targeted audience. Increasingly, the same applies for any digital transmission.

Ownership Restrictions and Media Concentration

Almost beginning with the implementation of the dual broadcasting system, a lively discussion concerning the topic of media concentration had begun. As the Federal Constitutional Court had ruled, the purpose of concentration control was to safeguard plurality and diversity by preventing dominant opinion-forming positions. A private television provider nowadays in general can broadcast as many services as he intends to. Nevertheless, one broadcaster cannot control more than a 30 percent share of the general television audience. Recently leading German media houses had to learn, that related markets also have to be considered. In any case, media authorities are allowed to take measures in order to protect "variety".

Financing Public and Private TV

One main distinction between public and private television services is the different funding systems. As described above, public television is mainly financed by a fee that has to be paid by every owner of a television set. Besides that, public broadcasters are allowed to broadcast advertisements to a certain extent.

By contrast, private services have to finance themselves by commercials, sponsorship or other forms of advertising. Recently, several television services started to present so-called "Call-In" shows in order to create revenues by incoming phone calls. Further, several teleshopping channels are said to have reached break even.

Digitalization and Pay-TV

In Germany, analog transmission of television services still has outstanding importance. Due to the unique variety of Free-TV services offered in Germany, digital and Pay-TV services had merely a chance to succeed in business in the past. Nevertheless, since 1990 Premiere offers a digital Pay-TV platform. As a matter of fact it can be stated, that currently more and more television service providers apply for a digital television licence, mainly for inventing special interest channels. Those programs mostly become part of bundles promoted by Premiere or by cable network operators as Kabel Deutschland or Unity. Since a few years, terrestrial digital video broadcasting (DVB-T) has being implemented in Germany covering private and public TV as well. Recent discussions concern the legal framework of IP-TV offers and digital video broadcasting via handhelds (DVB-H).

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Energy

General

For decades competition was by force of law basically excluded from the German energy markets. The result was that several regional monopolies emerged. The market participants, mostly vertically integrated utilities, were acting on three levels: First there was a small number of companies (in the electricity sector now: RWE, E.ON, Vattenfall, EnBW) which operated the transmission grids and most of the power generating plants, second regional suppliers which supplied energy to both industrial and private consumers, third local companies usually owned by municipalities which operated most of the distribution grids and which served local small and medium businesses and private end customers.

German energy law underwent a first major change when the Energy Industry Act (Energiewirtschaftsgesetz) was amended in 1998. The amendments provided for the full liberalization of the electricity and to a large extent of the gas markets in one single step. Since legal protection of the regional monopolies ceased to exist, the period following this reform has been characterized by a significant number of foreign investments, mergers and strategic alliances by energy companies of all levels, by acquisitions of German utilities, and by the creation of an energy exchange.

While the beneficial results of the liberalization were manifest there had, however, been some disturbance of the markets by anticompetitive practices. Especially the problem of insufficient and discriminating third party access (TPA) to the networks had to be tackled. In addition, the acceleration directives, enacted by the European Union in 2003 in order to promote the single energy market, called for regulation of TPA, for unbundling of vertically integrated utilities, and for the introduction of regulatory authorities. Finally, a new German Energy Industry Act, implementing the acceleration directives, entered into force on July 13, 2005.

Third Party Access (TPA) and Network Regulation

The Energy Industry Act provides for the opening of the electricity and gas grid to competitors. A network operator must offer its grid for transmission to everyone in a transparent, non-discriminatory manner and according to objective criteria.

Up to the 2005 reform the conditions of access to the grid including the criteria for determining transmission tariffs (prices for using the grids) were contained in so-called "Verbändevereinbarungen" ("Agreements of Associations"). These were private contracts between different associations of industrial energy consumers, network operators and the industry ("negotiated TPA"). Since July 2005, however, the conditions of access to the grid and the methods for determining transmission tariffs are regulated by the new Energy Industry Act and several Ordinances ("regulated TPA").

The conditions and methods which regulate TPA to the electricity grid follow the former Agreement of Associations in many respects. In the gas sector, however, TPA is about to undergo a radical change: the new regime calls, for instance, for a genuine entry-exit system, for the possibility to trade capacity rights without restrictions, and for an effective congestion capacity management. Network operators of all levels are obliged to co-operate on a large scale in order to guarantee the functioning of the system. While there has been an agreement between the Federal Network Agency (Bundesnetzagentur) and the gas industry about TPA to the gas network the functioning of the new system needs to be proven (state: October 2006).

For the time being, network operators must obtain prior approval of their transmission tariffs. The regulatory authorities, however, are currently (October 2006) developing an incentive system which is to supersede the system of prior approval of transmission tariffs. Networks in a geographically integrated area fulfilling certain conditions as regards their object (so-called "property grids", serving, for instance, a certain industrial area) are not subject to regulation of TPA and transmission tariffs as described above.

Regulatory Authorities

The new Energy Industry Act established regulatory authorities for the electricity and gas sector on the federal level (Bundesnetzagentur, Federal Network Agency) and on the federal state level (regulatory authorities of the German Länder), the latter being responsible for smaller grids which do not extend beyond the borders of a federal state. The regulatory authorities are in charge of enforcing the Energy Industry Act including, for instance, TPA and prior approval of transmission tariffs.

Unbundling

In order to enhance transparency and to enable the regulatory authorities to supervise the markets effectively, the new Energy Industry Act requires electricity and gas network operators to be independent from their vertically integrated parent companies: the network has to be operated by a separate legal entity (however not in separated ownership), and the personnel of the network operator has to be sufficiently separated from the other entities of the group in order to avoid conflicts of interest ("legal and management unbundling"). These rules do not apply to networks with less than 100.000 customers connected to their grid.

Concessions for Lines

Municipalities are obligated to offer on a contractual and non-discriminatory basis the use of public property for laying and operating lines (including remote-control lines to control system and ancillary units) for the direct supply of energy to end customers within the municipality. Energy companies must in return pay concession fees for this right of way. The amount of fees per kilowatt-hour depends on the number of inhabitants of the municipality. Details, esp. on calculation of concession fees, are regulated in the Ordinance on Concession Fees.

Terms and Conditions of Energy Supply Contracts

The relationships between energy companies and private end customers ("household customers") are regulated by ordinances which cover in particular the conclusion, content and termination of energy supply contracts with household customers. They do not apply to energy supply contracts with other customers (i.e. industrial consumers). Some provisions are nevertheless sometimes referred to in those contracts. The details of how to connect end consumers to the low voltage and low pressure grids and how the grid connection may be used are regulated by additional ordinances which cover, inter alia, the liability of network operators for disruptions of supply. The conclusion of contracts is also regulated by the provisions of the German Civil Code (Bürgerliches Gesetzbuch, BGB).

Energy from Renewable Resources

The Act regarding the Priority of Energy from Renewable Resources (Erneuerbare-Energien-Gesetz) entered into force on August 1, 2004. This Act provides for the obligation of grid operators to connect facilities which produce electricity from renewable resources to their grid and to purchase such electricity. The act guarantees that a certain minimum price is paid to the generator of electricity from renewable resources by the grid operator depending on the source of energy fed into the grid.

The Act on Maintaining, Modernizing and Increasing the Combined Use of Heat and Power (CHP) (KWK-Modernisierungsgesetz) came into effect on April 1, 2002 and will remain in force until December 31, 2010. This act is to promote the use of CHP stations in Germany. It obligates grid operators to connect CHP facilities to their grid, to purchase the electricity generated by these, and to pay a certain surcharge in addition to the price agreed between the parties.

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Construction Law

Architects and Engineers – General

Under existing building law, the services of an architect must be used to realize and implement a building project. In collaboration with the builder and with other specialists (e.g. structural/construction engineers, consulting engineers for technical systems, etc.), the architect develops the idea for the building project and its realisation.

Scope of Services and Fees

The scope of services depends on the architect's contract according sec. 631 seq. of the German Civil Code (BGB) in conjunction with the Scale of Architects' and Engineers' Fees of September 1976, last amended in 1995 (Honorarordnung für Architekten und Ingenieure, HOAI). The HOAI divides up an architect's performance into descriptions and stages of performance. The HOAI is not contract law, rather a sort of price regulation. Hence, it does not govern the terms of architect's contracts, but lays down certain pricing rules for agreed contractual terms. That is why the parties are not required to stipulate in a contract all the various stages for performance. However, to avoid ambiguities, it is advisable to define each stipulated element of performance in accordance to the project requirements. However, the question is whether the HOAI is also applicable if a foreign architect is involved in a German construction project or a German architect in a foreign construction project; this issue is not regulated by law and is highly disputed.

There are some additional rules that apply to fee agreements. Fees can only be effectively fixed by act of party when the contract is awarded, after which they cannot be changed even by act of party. The minimum rates laid down in the HOAI may only be undercut in exceptional cases. If contractual fee arrangements are invalid because the requirements are not met, the minimum rates laid down in the HOAI apply.

Organisation (Phases)

The organisation of the planning stage follows indirectly from the HOAI, according to which it is divided up into nine basic services (phases):

- basic calculations (clarification of requirements, consultation on scope of entire project);
- initial planning (analysis of basic situation, harmonization of objectives, etc.);
- draft planning (detailed work on the planning concept, step-by-step working out of the solution in draftsman's terms, etc.);
- planning approval (preparation of documents for submission as required by public law for obtaining approval, etc.);
- works plan (working out in detail the results of phases 3 and 4, etc.);
- preparation of placement of order (calculation and collation of quantities as the basis for drawing up a description of work, making use of the contributions of others involved in the planning, etc.);
- collaborating on the placement of order (collation of documents on conditions for all types of work, obtaining of quotations, etc.);
- project supervision (supervising the implementation of the project for compliance with building approval or consent, etc.);
- project supervision and documentation (physical inspection of project to identify defects, etc.).

Timing

The contract usually does not stipulate a deadline to be observed by the architect or engineer. This is being considered to be one of the main obligations of the builder. If, for example, the architect fails to provide the works plan within a reasonable period of time and this circumstance leads to the postponement of the contractual deadline, the principal may successfully sue for damages if it can prove that the delay was caused by the architect's actions.

Liabilities and Insurance

The builder assumes liability in relation to third parties: he alone is responsible to the authorities and other third parties involved. In relations inter se, the liabilities are divided up among those involved the planning, who in turn are responsible to the builder under their contracts for work and services. The architect, however, bears chief responsibility for the planning and project supervision.

The German Civil Code provides for 5 year liability on the part of the architect/engineer for hidden or apparent defects. The 5 year period commences on the day of acceptance of the services of the architect, i.e. usually after the conclusion of the project supervision and documentation stage. In the event of liability for willful default, the liability is subject a 10 year limitation period.

Mistakes made at the planning or project supervision stage are in most cases covered by the architect's liability insurance. As a rule, every architect has such a policy, as otherwise he is not authorized to submit building particulars and plans.

Termination

The contract usually includes special clauses which entitle both parties to terminate the contract. In the absence of a contractual provision, both parties are entitled to terminate the contract with cause, if the other party breaks contractual obligations and/or endangers the success of the project.

The architectural or engineering contract may be terminated at any time by the principal without cause. In this case, the principal has to pay damages to the architect. Contracts drafted by the architect normally provide for a lump sum of 60 % of the fees relating to

the uncompleted services to be paid of the architect. As the Federal Appeal Court decided at the beginning of 1996 that these contractual clauses are not valid, the architect is now forced to explain and to prove the actual damage caused by the termination of the contract.

Intellectual Property Rights

The Copyright Act (Urhebergesetz, UrhG) protects artistic works, works of architecture and applied art and the plans for such works, and illustrations of a scientific or technical nature, such as drawings, plans, maps, sketches, tables and three-dimensional representations. The sole criteria for this is not the pursuit of artistic end, but whether a personal intellectual creation has been produced. Thus, the planning and construction of buildings are, as a rule, protected by copyright.

Whether in any particular case the architect has granted any rights to use his copyrights (especially with regard to alterations, extensions, renovation of the building) depends on the contractual purpose in the absence of any express agreements to that effect. In general, however, it is safe to say that, if the architect has been entrusted with all the architectural work until completion of construction, he is not entitled to grant any such rights. Instead, the architect may subsequently exercise his right to imitate his own work.

Building Contracts – General

Building contracts in Germany are generally governed by sections 631 to 651 of the German Civil Code). However, these provisions are only dealing with "contracts for work" in general and cover a wide range of contractual agreements, not necessarily only classical building contracts. Therefore, very often the VOB/B (Vergabe- und Vertragsordnung für Bauleistungen, Teil B: Allgemeine Vertragsbedingungen für die Ausführung von Bauleistungen – Award and Construction Contract Rules, Part B: General Contractual Conditions for the Execution of Building Works) is being incorporated into a building contract. The VOB/B contains provisions with regard to the legal relationship between the principal and the contractor and is "tailor-made" for building contracts. Since the provisions of the VOB/B constitute general terms and conditions the content of every single stipulation can be subject to the restrictions laid down in sections 305 to 310 BGB; in case of violation against these priciples these provisions could therefore be invalid. However, this is not the case if the VOB/B is agreed "as a whole", i.e. without any essential changes.

There are different types of contractors, e.g. the general contractor (Generalunternehmer) who performs all kinds of building work for a construction, but usually transfers substantial parts of his work to sub-contractors (Subunternehmer). If the general contractor does also prepare the overall planning it is referred to as total contractor (Totalunternehmer). A general contractor that does not carry out any of the building work himself is called Generalübernehmer.

Scope of the Building Work

The scope of the building work owed is defined in the building specification normally contained in an attachment to the contract. "Additional services" which are closely connected to the building work are included within the contractual scope of the building work even if it is not explicitly stated (see for example section 4.1 VOB/C). Change requests regarding the scope of the building work owed are quite common. Therefore, agreements on additional work (Nachträge – supplements) are usual and of significant importance. At the time additional work and therefore a possible supplement is in question, the principal normally is not able to choose another contractor because of the advanced construction process. This often results in high priced supplements. A careful planning of the whole project in advance can help to avoid such expensive supplements.

Remuneration

There are various types of contracts with regard to remuneration provisions, e.g.:

- Unit-price contract (Einheitspreisvertrag): the remuneration for work is the product of the measured quantity and the fixed unit price. However, according to the VOB / B the single unit price can be dependent on the total quantity.
- Lump-sum contract (Pauschalvertrag): a total price is agreed on in advance for the entire scope of work to be exercised. As a consequence the remuneration to be paid is in general independent of the actual work exercised.
- Hourly-rate contract (Stundenlohnvertrag): the remuneration is based on the amount of time spent by the contractor. This type of contract is very rare and normally only used for smaller projects or when agreeing on additional work occurring during the construction process.
- Cost-plus contract (Selbstkostenerstattungsvertrag): the remuneration covers the original cost (Selbstkosten) to which a surcharge for risk and profit is added.

According to section 641 BGB the remuneration is due upon acceptance of the work. A final invoice (Schlußrechnung) is no condition precedent for the payment of the remuneration. In contrary, if the parties agreed on the VOB/B, the final payment (Schlußzahlung) is due after the acceptance of the work, the submission of a verifiable final invoice and the check of the final invoice by the principal (at the latest two months after receipt of the invoice). Part-payments on account (Abschlagszahlungen) can be claimed by the contractor before.

Passing of Risk/Acceptance

Until final acceptance of the building work the contractor bears the risk of accidental loss or destruction and deterioration of the building work. Once the building work has been finally accepted, the risk passes to the principal. Acceptance in terms of section 640 BGB means that the principal accepts the building work as performed in accordance with the contractual provisions and without substantial defects. Very often a so-called formal acceptance (förmliche Abnahme) is required.

Liability for Defects

In case of defects the principal/customer may (partly dependent on certain further preconditions):

- demand supplementary performance,
- remove the defect himself and demand reimbursement of the necessary expenditure
- terminate the contract or reduce the remuneration
- claim compensation or reimbursement of wasted expenditure.

If a defect is caused by several persons (e.g. contractor and architect), they can be held jointly liable.

Delay

If the contractor fails to carry out the building work owed within the agreed time limit, the principal can – in general after setting an additional period of time for performance – withdraw from the contract. Under certain preconditions the principal has also a claim for compensation. Very often a contractual penalty is agreed on in the building contract.

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Information Technology (IT) and IT Compliance / IT Governance

Doing business in Germany in the sector of information technology (IT) involves two main legal issues that are very important for the software industry respectively the provision of IT services to customers based in Germany. These IT-related topics are the protection and the use of software as well as the treatment of software licences under German law.

However, also companies that do not primarily act within the IT sector show a growing interest and awareness for another "IT-related" issue, namely the observance of IT Compliance and IT Governance being an integral part of Corporate Compliance.

Protection of Software in Germany

The provenience for software protection can be found in the German Copyright Act (Urhebergesetz, UrhG) which, however, contains only a few specific provisions for software protection, i.a. in Secs. 2 and 69 lit. a et seq. UrhG. However, this copyright protection for software is not unlimited at all. For example, the copyright granted under German law would not provide sufficient protection against the independent development of the same software solution by a third party. Also, the UrhG does not grant protection against the utilization of the concept of the software by third parties unless the identical source code or object code is being used. Furthermore, if a software developer produces a software specifically developed for the ordering party, it can be questionable whether such software production means that the IT provider loses its right to distribute this piece of software completely or whether he shall still be entitled to sell the same software to third parties. A little supplemental protection of software can be achieved under the German Act against Unfair Practices (Gesetz gegen den Unlauteren Wettbewerb, UWG) that may under certain further circumstances protect software against copying and plagiarism.

In some rare cases, software may also be patented according to the German Patent Act (Patentgesetz, PatG). However, the software itself can not be subject to patent protection because a patent will only be granted for a computer-implemented invention with a technical contribution. At present, the rulings and court decisions in Germany and Europe are not uniform concerning the requirements for such technical contribution. The former proposal for a directive on the protection of computer-implemented inventions by patents made by the European Commission would have harmonized such possibility to protect software by patents within the EU member states. However, the legislative procedure for this EU directive has not been brought to an end.

Software Licence Agreements

Under German law there is no legal category of agreements like "software agreement" or "licence agreement". Rather, under German law, the provision of IT services and the delivery of software have to be classified into the existing categories of agreements under the German Civil Code (Bürgerliches Gesetzbuch, BGB). This very basic classification is relevant for topics like warranty, liability, acceptance, due date of remuneration, partial payments, statute of limitations, the right of elimination of defects by oneself, etc. However, the German Civil Code contains diverse provisions for the different categories of agreements with respect to these topics which do not always fit to the special requirements of software contracts.

A licence agreement about standard software is, for example, classified as a purchase agreement in terms of the BGB, if the software is delivered as is for a one-time payment. If the software is being provided for a limited period of time with recurring payments, the provisions for rental agreements may apply. This could mean that the licensor owes permanent operativeness of the software during the term of the agreement, whereas the seller of software only has warranty obligations for a limited time period of two years.

Service Level Agreements

The provision of IT services other than the licensing of software is often subject to comprehensive Service Level Agreements (SLA) that define and modify the provision of IT services and usually foresee penalties in case of underperformances. Such SLA have to be drafted in accordance with the general rules of the BGB to avoid the nullity of the respective regulations.

In essence, this means that the correct interpretation and drafting of software and IT-related contracts have to observe the special rules and principles that are not only laid down in statutory law but also by the courts. This is also the case for standard licence conditions delivered in connection with open source software (e.g. some of the stipulations contained in the General Public License (GPL) would be considered void under German law).

Insolvency

Another very important factor not to be neglected in connection with the use of software is the protection of usage rights for the software in case of bankruptcy of the IT provider respectively the licensor. If the licensor becomes insolvent or an administrative receiver is being appointed over the licensor's assets, Sec. 103 German Insolvency Act (Insolvenzordnung, InsO) stipulates that the receiver may terminate the permanent licence agreement. In case the software contract has to be regarded as a licence agreement

(cf. the evaluation made above), the usage rights to the software would automatically extinguish upon the discretion of the receiver unless the parties have entered into an escrow agreement about the rights to the source code of the software. However, even software escrows may not always provide for sufficient protection of the core systems, because such escrows may also be subject to the mandatory rights of the receiver under the InsO. To be on the safe side, it can be advisable to add regulations about an usufruct regarding the source code into the software licence agreement.

IT Compliance Issues

Finally, doing business in Germany does not only mean that companies have to comply with all general rules laid out in this Guide (so-called Corporate Compliance, cf. above). Rather, companies also have to make sure that their information technology (IT) is in full compliance with statutory law and IT Governance requirements.

The so-called IT Compliance is not limited to being responsible for copyright issues although it is very much advisable to conduct internal audits from time to time in order to compare install counts to the existing licence agreements for software. This is especially the case in Germany because under German copyright law software publishers may – directly or through third-party associations – conduct audits with little or almost no evidence of noncompliance on the company's part. In this case, businesses may receive a notice that they must prove compliance with the licenses granted, or law enforcement officers may appear unexpectedly. Currently, experts in Germany predict an increasing probability that companies will be subjected to external software audits by enforcement organizations. In case a company is found in violation of intellectual property rights, this business is facing back-payment licence fees at punitive levels plus additional damages.

Furthermore, IT Compliance also includes the obligation for companies doing business in Germany to comply with the archiving rules set out in Sec. 257 German Commercial Code (Handelsgesetzbuch, HGB) and the General Tax Code (e.g. Secs. 146, 147 Abgabenordnung, AO). This means that the company and its IT systems have to observe the so-called "Generally Accepted Electronical and Optical Storage Principles" (Grundsätze DV-gestützter Buchführungssysteme, GOBS) and the "Principles for Digital Tax Audits" (Grundsätze zum Datenzugriff und zur Prüfbarkeit digitaler Unterlagen, GDPdU) issued by the Federal Ministry of Finance. As these guidelines for archiving may also be applicable to emails and attached documentation it might be necessary to adopt the data retention policies in place.

IT Governance and Risk Management

Although there are no specific law provisions (safe to data protection requirements set out above) requiring good information technology practices or a specific set of measurements for IT compliance it is undisputed that in order to avoid personal liability, but also to comply with due care requirements, the board of directors respectively the directors of a large GmbH are required to install a monitoring and control system that allows early detection of incidents or events that could put the existence of the company at risk (analogy to sec. 91 subsec. 2 AktG respectively sec. 43 subsec.1 GmbH). Therefore, a company must satisfy certain quality and security requirements for its information infrastructure. This also covers the prevention of risks resulting from erroneous input and processing of data.

Hence, without having a special law or regulation requiring IT compliance of a certain kind, management of a company has to establish efficient measures for sufficient control over its IT systems in order to enable effective IT risk management. This means that management must ensure the existence of an internal (in case of a third party IT provider external) control system or framework to support the various business processes. Mostly, those control objectives can be achieved by built-in application control functionality. This functionality is commonly found in integrated ERP environments, such as SAP. In cases of lacking this functionality, the control objectives may require a combination of manual and automated control procedures to satisfy the control objective. This can be done by appointing an Information Security Officer (ISO) to coordinate the activities concerning the secure handling of data.

Installation and Observance of IT Standards

In light of the general rules outlined before companies are well advised to establish an IT-supported risk and service management that will prevent incidents from occurring or at least minimize the potential danger. In order to comply, companies may rely on industry standards such as COBIT (Control Objectives IT), service management rules like ITIL (IT Infrastructure Library), the "IT Grundschutz Manual" (IT-Grundschutz-Kataloge) issued by the Bundesamt für Sicherheit in der Informationstechnik (BSI) or other compliant processes (e.g industry standards like BS 7799 respectively ISO 9001, ISO 15000 and ISO 17799 which have in the meantime merged into ISO 27001). Applying these IT standards can be a key indicator to IT Compliance and IT Governance. However, under statutory law there are no minimum standards or specific requirements to be met. Hence, any form of efficient IT risk management (including an IT Continuity Plan to ensure availability of relevant data) can be in compliance.

The following principles may serve as a guideline for the necessary control mechanisms:

- Controls related to the initiation, recording, processing and reconciling of account balances, classes of transactions, disclosures and related assertions included in the financial statements;
- Controls related to the initiation and processing of non-routine and non-systematic transactions; as well as to the selection and application of accounting policies;
- Controls related to the prevention, identification and detection of fraud;
- Company-level controls, including the control environment and controls over the period-end financial reporting process as well as controls over procedures used to enter transaction totals into the general ledger and to record recurring and non-recurring adjustments to the financial statements (e. g. consolidating adjustments, report combinations and reclassifications).

Third Party Provider

The implementation of policies and procedures as described before is also mandatory in case the IT services are not being provided in-house, but by a third party IT supplier. A company therefore must oblige all third parties providing IT services to comply with those key elements. Arrangements involving third party access to the company's information processing facilities must be based on a formal contract containing, or referring to, all the security requirements above to ensure compliance with the company's security and information handling policies and standards. When agreeing contractual relations with third parties, the company must also safeguard that the standards implemented by the service provider are at least equal to those implemented within the company. Additionally, the following topics should be included into agreements with the company's IT provider or should be installed as in-house guidelines:

- Information security policy;
- Service Level Agreements (SLA) or policies for availability, reliability, performance, levels of support, continuity planning, etc.
- Asset protection, including procedures to protect organisational assets, including information and software;
- Procedures to determine whether any compromises of the assets, e. g. loss or modification of data, has occurred;
- Restrictions on copying and disclosing information;
- Access control regulations
- Establishment of an escalation process for problem resolution;
- Regulations regarding hardware and software installation and maintenance;
- Change management procedure
- Reporting and notification of security incidents

Finally, companies should be aware that the life cycles of IT systems are getting shorter along with the fast technical improvement and that therefore the requirements for IT compliance are subject to ongoing change. However, IT Compliance and IT Governance should not be regarded as a burden. Rather, establishing service-orientated structures also within the IT (and such complying with IT Governance requirements) can also tremendously contribute to the company value.

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