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一、新修改专利法获通过 法定赔偿额上限提高至 500 万

2020.10.18

Newly Revised Patent Law Adopted and Statutory Damages Cap Increases to CNY5 Million

日前，第十三届全国人民代表大会常务委员会第二十二次会议审议通过《关于修改〈中华人民共和国专利法〉的决定》（下称《决定》），自 2021 年 6 月 1 日起施行。

The *Decision on Revising the Patent Law of the People's Republic of China* (the "Decision") has been recently adopted upon deliberation at the 22nd session of the Standing Committee of the 13th National People's Congress and will take effect as of June 1, 2021.

《决定》主要对加强对专利权人合法权益的保护、促进专利实施和运用、完善专利授权制度等三方面内容进行了修改完善。其中，《决定》新增了惩罚性赔偿制度，即对故意侵犯专利权，情节严重的，人民法院可以在按照权利人受到的损失、侵权人获得的利益或者专利许可使用费倍数计算的数额 1 到 5 倍内确定赔偿数额。同时，提高了法定赔偿额，将法定赔偿额上限提高至 500 万元、下限提高至 3 万元。《决定》还新增了药品专利纠纷早期解决机制，以更好地平衡专利权人、仿制药企业和社会公众利益；为补偿新药上市审评审批占用时间，新增关于药品专利期限补偿的规定等。



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The *Decision* makes main revisions and improvements in three aspects: Firstly, the *Decision* strengthens the protection of the legitimate rights and interests of patentees, promotes the exploitation and use of patents, and improves the patent authorization system. Among others, the *Decision* adds a punitive damage system, under which in the case of the intentional infringement of a patent right, if the circumstances are serious, a people's court may determine the amount of damages as one to five times the amount calculated based on the losses suffered by the relevant patentee, the profits obtained by the relevant infringing party, or the appropriate established royalties of such patent. Meanwhile, the amount of statutory damages increases, with the upper and lower limits being raised to CNY5 million and CNY30,000 respectively. In addition, the *Decision* adds an early resolution mechanism for drug patent disputes to properly balance the interests of patentees, generic drug manufacturers, and the public; to compensate for the time occupied by the review and approval of new drugs to be launched to the market, provisions on compensation for the drug patent term and other provisions are added.

(Source: <https://www.chinacourt.org/index.php/article/detail/2020/10/id/5529023.shtml>)

二、全国人大常委会就个人信息保护法草案征求意见

2020.10.22

NPC Standing Committee Seeks Comments on Draft Law on Personal Information Protection

近日，第十三届全国人民代表大会常务委员会第二十二次会议对《中华人民共和国个人信息保护法（草案）》（下称《草案》）进行了审议，并对外公布全文，面向社会征求意见，征求截止于 11 月 19 日。

The full text of the *Law of the People's Republic of China on Personal Information Protection (Draft)* (the "*Draft*"), deliberated at the 22nd session of the Standing Committee of the 13th National People's Congress ("NPC"), has recently been released for public comments by November 19, 2020.



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《草案》主要包括：一是明确适用范围；二是健全个人信息处理规则；三是完善个人信息跨境提供规则；四是明确个人信息处理活动中个人的权利和处理者义务；五是关于履行个人信息保护职责的部门。

The *Draft* mainly touches upon contents in five aspects: 1. clarifying the scope of application; 2. improving the rules for personal information processing; 3. perfecting the rules for the cross-border provision of personal information; 4. specifying the rights of individuals and obligations of processors in personal information processing activities; and 5. describing the department fulfilling the duty of protecting personal information.

其中，《草案》确立以“告知-同意”为核心的个人信息处理一系列规则，要求处理个人信息应当在事先充分告知的前提下取得个人同意，并且个人有权撤回同意；重要事项发生变更的应当重新取得个人同意；不得以个人不同意为由拒绝提供产品或者服务；对基于个人同意以外合法处理个人信息的情形作了规定。《草案》还对跨境提供个人信息的“告知-同意”作出更严格的要求。

In particular, the *Draft* establishes a series of rules for personal information processing with "notification - consent" mode as the core, requiring that the personal information should be processed on the premise of fully notifying the individuals in advance. Upon obtaining their consent, the individuals have the right to withdraw the consent; in case of changes in significant matters, the consent shall be obtained again from the individuals. Provision of products or services may not be refused on the grounds that the individuals refuse their consent. The *Draft* also sets out provisions on the legal processing of personal information other than those subject to the consent of individuals. And the *Draft* puts forward stricter requirements on the "notification - consent" for cross-border provision of personal information as well.



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(Source: <http://www.npc.gov.cn/flcaw/userIndex.html?lid=ff80808175265dd401754405c03f154c>)

三、人社部加强共享用工指导和服务 促进共享用工有序开展 2020.09.30

MOHRSS Strengthens Guidance and Services for Shared Employment to Promote Its Orderly Development

日前，人力资源和社会保障部办公厅发布《关于做好共享用工指导和服务的通知》（下称《通知》）。

The General Office of the Ministry of Human Resources and Social Security ("MOHRSS") has recently issued the *Circular on Working Effectively on Guidance and Services for Shared Employment* (the "Circular").

《通知》包含支持企业间开展共享用工、保障企业用工和劳动者工作的自主权、妥善处理劳动争议和查处违法行为等八部分内容。其中，《通知》规定，各级人社部门指导员工富余企业（下称“原企业”）在将劳动者安排到缺工企业工作前征求劳动者意见，与劳动者协商一致。共享用工期限不应超过劳动者与原企业订立的劳动合同剩余期限。

The *Circular* contains eight parts including supporting the shared employment among enterprises, guaranteeing the autonomy of enterprises to recruit employees to work, handling labor disputes, and investigating and handling illegal acts in a proper manner. Among others, the *Circular* requires that departments of human resources and social security at all levels shall guide an enterprise with surplus employees (the "former



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enterprise") to seek the opinions of and reach a consensus with employees before assigning them to an enterprise in shortage of employees. And the period of shared employment shall not exceed the remaining period of the labor contract concluded between employees and the former enterprise.

同时，劳动者在缺工企业工作期间，缺工企业未按照约定履行保护劳动者权益的义务的，劳动者可以回原企业，原企业不得拒绝。《通知》还明确，对通过共享用工稳定职工队伍的企业，阶段性减免社保费、稳岗返还等政策可按规定继续实施。

Meanwhile, during the period when the employee works for the enterprise he or she is assigned to, if such enterprise fails to perform the obligation to protect the rights and interests of the employee as agreed, the employee may return to the former enterprise, and the former enterprise shall not refuse. The *Circular* also specifies that enterprises that stabilize their workforce through shared employment may still be subject to such policies as phased reduction or exemption of social insurance premiums and refunds for stabilizing employment as required.

(Source: http://www.mohrss.gov.cn/gkml/zcfg/gfxwj/202010/t20201010_392537.htm
1)

四、国家药监局优化进口医疗器械产品在我国境内企业生产事项 2020.09.27

NMPA Optimizes Matters Concerning Production of Imported Medical Device Products by Enterprises within China

近日，国家药品监督管理局发布《关于进口医疗器械产品在中国境内企业生产有关事项的公告》（下称《公告》），自发布之日起施行。



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The National Medical Products Administration ("NMPA") has recently promulgated the *Announcement on Matters Concerning the Production of Imported Medical Device Products by Enterprises within the Territory of China* (the "*Announcement*"), with effect from the date of promulgation.

根据《公告》，国家药监局对已取得进口第二类、第三类医疗器械注册证的产品在我国境内生产申请产品注册时，基于医疗器械科学监管的原则，在主要原材料和生产工艺不发生改变、质量管理体系保持一致的前提下，认可部分原申报材料用于境内生产产品的注册申报。

According to the *Announcement*, when a product registration application is made for the home production of products accredited with the registration certificate for Class II and Class III imported medical devices, the NMPA recognizes part of registration declaration of products produced within the territory of China with the original declaration materials in the principle of scientific regulation of medical devices and on the premise that the main raw materials and production processes remain unchanged and the quality management systems are consistent.

《公告》进一步对注册要求、注册体系核查要求、上市后监管要求等事项进行了规范，明确进口医疗器械注册人在中国境内设立的外商投资企业作为注册申请人，向药品监督管理部门提交境内医疗器械注册申请。《公告》还确立了境内企业和境外企业的一致性原则，对于境内企业投资境外企业并在境内企业生产同样适用。

The *Announcement* further regulates registration requirements, registration system verification requirements, post-marketing regulatory requirements and other matters. It clarifies that foreign-invested enterprises established by the registrants of imported



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medical devices within the territory of China shall serve as registration applicants and submit applications for registration of medical devices within the territory of China to the drug administrative departments. The *Announcement* also establishes that the principle of consistency between the domestic and overseas enterprises is equally applicable to domestic enterprises investing in foreign enterprises and producing in domestic enterprises.

(Source: <https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20200925152407171.html>)

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