生物多样性法：IP 商品化及利益分配
Commercializing IP and benefit sharing under India's BD Act

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印度通过实施严格的法律及政策，竭力保护和保存其生物多样性。

在印度，使用或获取生物资源的专利申请必须遵守《生物多样性法（2002）》才能获得生物资源。该法第六条规定，对于任何基于印度生物资源的研究或者信息的发明，申请人要获得其知识产权必须获得国家生物多样性管理局（National Biodiversity Authority [NBA]）的预先核准。据此，印度专利局在根据《生物多样性法》对上述要求进行认定时开始变得谨慎。

《生物多样性法》另一项重要的规定在第 21 条，其对于使用印度生物资源的知识产权发明在商品化过程中所产生利益的公平分配进行了规定。

起草这条规定的立法目的是确保印度的生物资源一旦以商品化的目的被开发利用，所产生的利益必须为这些生物资源的合法所有者获得，这些所有者多数为当地居民。同样地，任何通过开发印度生物资源以创造知识产权的发明都必须遵守《生物多样性法》第六条规定，并必须依据《生物多样性法》的要求分配该知识产权商品化所产生的利益。

尽管第 21 条规定对于开发印度生物资源的知识产权发明在商品化中所产生利益的公平分配进行了规定，但是并未提及这些利益必须以何种方式分配，导致这项规定模棱两可。

为了让《生物多样性法》的目的得以实现，印度中央政府最近发布了《关于生物资源及相关知识获取与惠益分享规定的指引（2014）》。这份通知解决了现存的决定合同各方利益分配中存在的模糊问题。该《指引》规定，申请人和 NBA 之间的利益分配可以采用货币或非货币的方式实现。

货币利益分配

货币利益分配包括合同各方同意通过以下方式分配利益的情况：(1) 预付款；(2) 一次性支付；(3) 里程碑付款；(4) 累计使用费及利益的分配；(5) 授权费分配；(6) 对国家、州以及当地生物多样性基金出资；(7) 为印度境内的研发项目融资；(8) 与印度机构和公司设立合营企业；(9) 享有相关知识产权的共同所有权。

此外，在知识产权商品化的情况下，应该通过以下方式确定利益分配标准：

1. 如果申请人将流程、产品或者发明商品化，货币利益分配比例应基于行业情况设定在 0.2% 到 1.0% 之间，并应通过年度的出厂销售总额减去政府征税额计算得出。
2. 如果申请人将流程、产品或者发明转让或授权给第三方进行商品化，申请人应将所收费用的 3.0% 到 5.0%（包括授权费和转让费在内的任何形式）以及每年基于行业情况从受让人或被许可人处获得的使用费的 2.0% 到 5.0% 上缴至 NBA。

非货币利益分配

非货币利益分配方式包括进行基建和开发工作，加强技术转移、教育培训合作的能力，增强当地居民创收能力的贡献，设立风险投资基金，提供奖学金或者财务援助等。

> “《生物多样性法》之立法目的在于确保……生物资源所产生利益的公平分配”

NBA 利益分配

对于 NBA 从申请者处所征利益的分配方式，《指引》也提供了清晰的说明。在 NBA 颁发许可时，可以从申请者上缴的利益中获得 5%，在该 5% 的收益中，NBA 可以保留其中的 50%，而其余的 50% 份额则分配给相关的国家生物多样性委员会（State Biodiversity Boards [SBB]）作为行政管理收费。申请者上缴的累计利益中 95% 应给予相关的生物多样性管理委员会（Biodiversity Management Committee [BMC]）和 / 或利益申请人。《指引》同样明确，在利益申请人明确的情况下，这些利益应该直接分配给他们。如果无法确认利益申请人，这些资金应用于保存或维护生物资源，以及提高生物资源所在地居民的生活水平。

同样，《指引》也规定了 SBB 对累计利益的分配方式：在 SBB 授予许可时，有权获得累计利益的 5% 作为其行政管理收费，其余 95% 分配给相关的 BMC 或者利益申请人。如果未能确认利益申请人，这些资金将会用于保护、维持当地生物资源以及改善生物资源所在地居民的生活。

总结

《生物多样性法》之立法目的在于确保生态资源的可持续利用，以及生物资源所产生利益的公平分配。对于商品化的发明，印度中央政府发布的《指引》清晰规定了来自生态资源的利益应如何公平分配。因此，印度政府所付出的努力和采取的措施保证了《生物多样性法》的严格实施，防止得自于印度的生物资源的过度开发，并保护谨慎利用这些资源为生的当地居民的利益。■

India has made substantial efforts to protect and conserve its biological diversity by implementing stringent laws and policies.

The patent applications in India that use and/or access biological resources need to conform to the provisions of the Biological Diversity (BD) Act 2002 for accessing biological resources. Section 6 of the BD Act requires an applicant to have prior approval from the National Biodiversity Authority (NBA) when applying for any intellectual property (IP) for any invention based on any research or information on a biological resource obtained from India. Pursuant to this, the Indian Patent Office (IPO) is also vigilant in taking cognizance of the requirements under the BD Act.

Another important provision of the BD Act is section 21, which provides for the equitable sharing of benefits arising out of commercializing an intellectual property rights (IPR) invention using biological resources originating from India. The legislative intent behind drafting this provision was to ensure that whenever the biological resources of India are exploited for commercialization, the benefit must reach out to the legitimate holders of these biological resources, which usually are the local communities.

Likewise any invention that exploits biological resources obtained from India for creating intellectual property must abide by section 6 of the BD Act and must share the benefits arising from the commercialization of such IP as per the requirements of the BD Act.

Although section 21 provides for the equitable sharing of benefits arising out of commercializing an IPR invention using biological resources originating from India, it fails, however, to address the manner through which the benefits must be shared, leaving this matter altogether ambiguous.

To keep the intentions of the BD Act alive, the central government recently issued a notification entitled Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations 2014. This notification resolves existing ambiguities while determining the quantum of benefit sharing between the contracting parties.

The guidelines provide that benefit sharing between the applicant and the NBA can be both monetary and non-monetary.

Monetary benefit sharing

Monetary benefit sharing includes where the contracting parties agree to share the benefits through the following ways:

i. Upfront payment;
ii. One-time payment;
iii. Milestone payments;
iv. Share of the royalties and benefits accrued;
v. Share of the licence fees;
vi. Contribution to national, state or local biodiversity funds;
vii. Funding for research and development in India;
viii. Joint ventures with Indian institutions and companies; and
ix. Joint ownership of relevant intellectual property rights.

In case of the commercialization of IPR, the criterion for benefit is ascertained in the following manner:

1. Where the applicant itself commercializes the process/product/innovation, the monetary sharing shall be in the range of 0.2% to 1.0% based on a sectoral approach, which shall be worked out on the annual gross ex-factory sale minus government taxes; or
2. Where the applicant assigns/licenses the process/product/innovation to a third party for commercialization, the applicant shall pay to the NBA 3.0% to 5.0% of the fee received (in any form including the licence/assignee fee) and 2.0% to 5.0% of the royalty amount received annually from the assignee/licencee, based on sectoral approach.

Non-monetary benefit sharing

The non-monetary benefit sharing includes undertaking infrastructure and development work, strengthening capacity for technology transfer, educational/training collaborations, and contribution to income generation for local communities, setting up venture capital funds, providing scholarships/financial aid, etc.

Sharing accrued benefits by NBA

The guidelines also impart clarity on the sharing of accrued benefits by the NBA from the applicant. When the NBA grants approval, it is entitled to 5% of the benefits from the applicants, and out of 5% the NBA retains 50% of the share and the other 50% is passed on to the concerned state biodiversity boards (SBBs) for administrative charges. A total of 95% of the accrued benefits from the applicant go to the concerned biodiversity management committee (BMC) and/or benefit claimers.

> “*BD Act is ... to ensure the fair and equitable sharing of benefits arising from biological resources*”

The guidelines also clarify that in circumstances where the benefit claimers can be identified, this amount should go to them directly. If the benefit claimers are not identified, this fund should be used to conserve/sustain the biological resource and promote livelihoods of the local people from where the biological resource is accessed.

Likewise, the guidelines also provide the sharing of accrued benefits by SBBs, and when an SBB grants approval, the SBB is entitled to retain 5% of the benefits accrued for their administrative charges, passing 95% to the concerned BMC/benefit claimers. In a case where the benefit claimers are not identified, this fund shall be used to conserve/sustain the biological resource and to promote livelihoods of the local people from where the biological resource is accessed.

Conclusion

The objective of the BD Act is to ensure sustainable utilization of biological resources, and to ensure the fair and equitable sharing of benefits arising from biological resources. The guidelines as issued by the central government clearly establish the manner in which fair and equitable benefit sharing of biological resources can be ascertained in inventions that are commercialized. Thus the efforts and steps being taken by the government ensure the strict implementation of the BD Act to prevent exploitation of biological resources originating from India, and also safeguard the interests of the local communities who make judicious use of such resources for their subsistence. ■

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