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Disclosure of Origin and Legal Provenance: The Experience and Implementation Process in South America

ICTSD Project on Genetic Resources

Manuel Ruiz Muller
Peruvian Society for Environmental Law

Introduction

The relationship between access to genetic resources and benefit-sharing (ABS) and intellectual property is based on recognition of the following principle: the granting of patents or other intellectual property (IP) rights over biodiversity related innovations should be conditioned on biodiversity components being acquired, obtained or accessed legally. In other words, inventions derived from biodiversity, including genetic resources, must be submitted to additional scrutiny that requires such resources to comply with national ABS laws and regulations regarding the protection of associated traditional knowledge (TK) if it were the case. This is the principle of disclosure of origin and legal provenance that determines the link between IP and ABS.

The idea of creating synergies between different legal regimes (IP and ABS and/or the protection of TK) raises considerable policy, economic, legal and practical challenges that have been addressed over time in various countries' laws and regulations. It has also been a matter for debate in international forums, such as the Conference of the Parties to the Convention on Biological Diversity (CBD),[1] the Council for the Trade Related Aspects of Intellectual Property Rights (TRIPS) and the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).

In order to contribute to a better understanding of this principle and overcome future challenges that may arise from connecting ABS, IP and TK, this document briefly analyzes the history of disclosure of origin and legal provenance and their development. It also reviews legal experiences in various countries and implementation in practice. Finally, it provides with some recommendations for improved application.

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[1] *For an initial reflection on the relevance and need for an International Regime on ABS, see, Ruiz, Manuel. The International Regime on Access to Genetic Resources and Benefit Sharing: In Search of the Right Direction. Policy and Environmental Law Series. SPDA, No. 17, January, 2006.*

General Context

Since their appearance in the Andean Community at the beginning of the 1990s,[2] disclosure of origin and legal provenance of genetic resources and TK have become firmly established in international and national discussions. They have also become important policy and legal issues in the IP and biodiversity debate.

One of the foundations for the linkage between ABS and IP can be found in the CBD, which determines that countries have common but differentiated responsibilities with respect to conservation and the sustainable use of biodiversity components. To comply with the objectives of the CBD, including the fair and equitable sharing of benefits from the use of genetic resources and TK, countries that are traditionally providers of biodiversity require user countries (those that transform resources through biotechnology and other processes) to adopt policy and normative measures and collaborate in the realization of and compliance with this objective.[3]

At a more practical level, this link is justified because of the serious difficulties countries of origin or providers of genetic resources face when monitoring what takes place once biodiversity components leave national jurisdictions and become part of complex research and development processes, usually in developed countries, with different actors involved and often over extended periods.

Disclosure of origin and legal provenance have been associated with the patent system, which requires appropriate disclosure of inventions in order for them to be replicated by a person skilled in the art. In this context, it is argued that if there is no disclosure of origin or legal provenance, the invention cannot be executed and, as a result, the right should not be granted.[4]

Brief Historical and Conceptual Background

Unlike other fields of intellectual property, the incorporation of disclosure into the debate of IP and patents, in particular, implies the success of the Southern, developing countries' agenda and their interests. The idea of disclosure and its consistent discussion worldwide and legal recognition in various laws, is one of the few examples of successful policy pressure originating in the South, the biodiversity rich area par excellence, and effectively permeating into and shaping international agendas.[5]

Debates on the potential connections between ABS, TK and IP started in the Andean Region in 1993, immediately after the CBD entered into force. At the time, a legal regime on access for genetic resources was being discussed and developed. It was under the framework of the Andean Community (AC) that disclosure of origin and legal provenance were proposed for the first time as part of specific public policies and in a normative/legal process.[6]

During the Andean process, participating countries and experts recognized the limitations of national ABS legislation to guarantee minimum levels of control and the realization of the fair and equitable distribution of benefits. Countries on their own, through their national laws and regulations, are unable to verify the destination of their genetic resources once those resources leave their jurisdictions. Also, they are not able to verify compliance with clauses or obligations established in ABS contracts. They are furthermore unable to monitor how their resources are being used during different stages of the research and development process. Therefore, they cannot guarantee that the benefits generated, either monetary or non-monetary, are distributed in a fair,

2 Regional social and economic integration bloc formed by Bolivia, Colombia, Ecuador and Peru. The Andean Community was founded in 1969, in Cartagena, Colombia and was originally known as the Andean Pact or Cartagena Agreement.

3 International legal regimes need to be, at the very least, complementary. This gives the global legal system coherency and the connection between ABS and intellectual property can be better understood.

4 Article 29(1) of TRIPS provides that "Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application".

5 The formation of the Group of Like-Minded Megadiverse Countries in Cancun, Mexico in 2002 (through the Cancun Declaration), is the best example of a group of countries united by common interests related to biodiversity, including in regards to the requirement for disclosure. Disclosure has been addressed through numerous interventions and declarations in many forums and opportunities by this Group. The Group is formed by: Bolivia, Brazil, China, Congo, Costa Rica, Colombia, Philippines, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, South Africa and Venezuela. For information on the Groups history and actions at the international level, see: http://www.lmmc.nic.in

6 For a detailed analysis of this policy/normative process, see, Caillaux, Jorge, Ruiz, Manuel, Tobin, Brendan (1999). Andean Regime on Access to Genetic Resources. Lessons and Experiences. WRI, SPDA, Lima, Peru.

effective and timely manner. This is the result of the physical and informational nature of genetic resources and the limitations of contracts in this regard.[7]

The limitations of stand-alone national ABS legislation led experts and countries to suggest that countries using genetic resources for research and development adopt measures that strengthen and contribute to follow up, compliance, monitoring, etc. In this context, the patent regime (patent application procedures, in particular) offers an interesting check point to verify compliance with ABS and TK legislation. It can also serve to determine and trigger the sharing of benefits and identify advances in the research and development process. It is important to note that while all countries tend to be users and providers of genetic resources at the same time, historically, the flow of resources from South to North has been especially notorious and evident.[8]

Finally, the idea of establishing a type of certificate of origin as an internationally accepted standardized instrument to make the proposal of disclosure operational, was also born during the Andean Community ABS development process.[9] In short, the idea is to disclose origin and legal provenance through this certificate.[10]

Insofar as the recognition of a certificate is not universal, to date there is no data available for countries having issued a certificate or evidence of intellectual property authorities having required it. There are laws and regulations in Costa Rica, the Andean Community, Brazil, Panama, etc. that refer to a certificate in general terms.

Not only can origin per se serve as evidence that national requirements on ABS and the protection of TK have been met, but also a certificate can contribute to supporting compliance with the general principles of the CBD, mainly regarding prior informed consent (PIC), mutually agreed terms or the distribution of benefits.[11]

Subsequently, the debates that took place within the Andean Community were replicated in other countries and at the international level, in the CBD, WIPO IGC, WTO, the ABS International Regime process, etc.[12]

Requirments for Dislosure of Origin and Legal Provenance and Their Legal Recognition in South America: Advances in Implementation

The requirement for disclosure of origin and legal provenance is expressed in different forms, but it is always aimed towards the identification of the geographical origin of a resource on one hand and verification of compliance with ABS conditions on the other.[13] This means that countries need to have ABS legislation in place that expressly demands the disclosure requirement.

7 For experts like Joseph Vogel, Economist and Professor of the University of Puerto Rico, the informational characteristic of genetic resources (widely recognized by scientists), has been underestimated and not taken into account in national and international policy and normative processes on ABS. Genetic resources are codified information: this is where the value and importance of genetic resources lies. As a result, inadequate legal and institutional frameworks have been designed. These frameworks have been ineffective to capture benefits derived from access to and use of genetic information. For details on this conceptual and practical approach, see, Vogel, Joseph. 1994. Genes for Sale. Privatization as a Conservation Policy. Oxford University Press, USA.

8 Countries in the South are net exporters of genetic resources (except in the case of resources used in agriculture). In the specific case of genetic resources for food and agriculture, (unlike the case of resources used in research and the development of pharmaceutical products and cosmetics), most countries are equally users and providers of such resources. Countries are unable to sustain their agriculture and guarantee long term food security based exclusively on native and local resources. This varies according to countries but is generally the rule. This is due to the historical flow of resources throughout commercial exchanges between regions and continents that intensified during the XV century. For a better understanding on the issue of "interdependence" in genetic resources for food and agriculture, see, Biber-Klemm, Susette, Cottier, Thomas (Editors). Rights to Plant Genetic Resources and Traditional Knowledge. Basic Issues and Perspectives. World Trade Institute, United Kingdom, 2006. Another excellent historical text on the flow of goods (including plants and animals) and services is, Bernstein, William. 2008. A Splendid Exchange. How Trade Shaped the World. Atlantic Books, London.

9 There are different names which have been given to the certificate: of origin, of legal provenance, of compliance or observance, etc. Basically, they all aim to verify compliance of norms in countries that supply, provide or facilitate access to genetic resources. By extension, it could also be used to verify compliance of national TK laws and regulations.

10 Possibly, the first article to make reference to a certificate of origin in this context is, Tobin, Brendan. Certificates of Origin: A Role for IPR in Securing Prior Informed Consent. In: Mugabe, Barber, La Viña, Henne, Glowka, (Eds). Access to Genetic Resources: Strategies for Benefit Sharing. IUCN, WRI, Acts Press, Nairobi, 1997.

11 On the application and viability of a certificate of origin, see, UNEP/CBD/WG-ABS/3/INF/5 The Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources: Preliminary Results of Comparative Analysis of Tracking Material in Biological Resources Centers and of Proposals for a Certification Scheme, (2005), available at http://www.cbd.int

12 Various countries, mostly developing countries rich in biodiversity, have presented to WIPO and TRIPS, information notes and position documents on ABS, TK and disclosure of origin in particular. These include documents such as: WT/GC/362 (October, 1999) that was the first document of this type presented by Bolivia, Ecuador, Nicaragua, Colombia and Peru, or IP/W/441 presented to the WTO by India, Brazil, Cuba, Thailand, Peru and Ecuador, to sustain the need to disclose the origin of biological resources in patent documents and/or genetic materials used; or the most recent WT/GC/W564/Rev.2 -TN/C/W/41/Rev. 2- IP/C/ presented to the TRIPS Council by Brazil, China, Colombia, Cuba, Pakistan, Peru, Thailand and Tanzania to modify the TRIPS Agreement to include disclosure of origin of biological resources and associated traditional knowledge (July 2006). See, http://www.wto.int. The CBD has generated interesting texts on the position of industrialized countries and private sector associations. See for example, UNEP/CBD/WG-ABS/4/4 available at http://www.cbbd.int. This is simply to reflect how the policy process is energized, through formal positions and documents from countries and institutions.

13 For more conceptual contributions on disclosure (legal nature, characteristics, trigger points, etc.) see, Chouchena-Rojas, Martha, Ruiz, Manuel, Vivas, David, Winkler, Sebastián (2005). Disclosure Requirements: Ensuring Mutual Supportiveness Between the WTO TRIPS Agreement and the CBD. IDDRI, CIEL, ICTSD, QUNO, IUCN. France. Likewise, a text by Professor Correa explains why it is perfectly valid and legally consistent under TRIPS, to propose the requirement for disclosure of origin and legal provenance. Correa, Carlos. Alcances Jurídicos de las Exigencias de Divulgación en el Sistema de Patentes y Derechos de Obtentor. Iniciativa para la Prevención de la Biopiratería. Año I, No. 2, Agosto de 2005, Lima, Perú.

This principle was first recognized expressly in a legal text in Peru in 1996. In this case, the principle applied to the regulation on the protection of new plant varieties.[14] Interestingly, the requirement for disclosure of origin of genetic resources and TK was initially part of the plant varieties protection regime (a UPOV-like system that is in force in the Andean Community) and not of the patent regime.[15] The adoption of laws for the implementation of the Peru-US Free Trade Agreement has also recently generated discussions regarding the need for modifications to Andean Community legislation on IP, specifically the patent regime and its disclosure provisions.[16]

A Brief Summary of Disclosure Provisions (and Certificates of Origin) in Legislation in Some Countries

Legislation	Content
Andean Community Decision 391 on a Common Regime on Access to Genetic Resources (1996)	The concession of intellectual property rights is conditioned to providing the patent office with a copy of the contract on access to genetic resources.
Biodiversity Law of Costa Rica No. 7788 (1998)	The National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the access authority before granting protection of intellectual or industrial property to innovations involving components of biodiversity. Applicants must always provide the certificate of origin issued by the competent authority and the prior informed consent.
Andean Community Decision 486 on a Common Regime on Intellectual Property (2000)	The protection of intellectual property elements shall be granted safeguarding and respecting the biological and genetic heritage, as well as the traditional knowledge of their indigenous, African-American or local communities. Granting patents on inventions created from materials obtained from such heritage and knowledge shall be conditioned to the material being acquired in accordance with international, community and national law.
Law 27811 on the Protection of TK in Peru (2002)	Patents granted for inventions involving TK are conditioned to the presentation of the contract or instrument that legitimizes access to or use of the TK.
Provisional Measure 2.186-16 on Access to Genetic Resource in Brazil (2001)	The granting of intellectual property rights on the genetic heritage is conditioned to presenting evidence of legal access.
Executive Decree 257 on Access to Genetic Resources in Panama (2006)	The competent office on access shall issue a certificate of origin and legal provenance to accompany the resource, a condition for intellectual property rights being granted.

14 Supreme Decree 008-96-ITINCI (1996) that regulates Andean Community Decision 345 on a Common Regime on the Protection of the Rights of Breeders of New Plant Varieties (1993) establishes in Article 15 that the application to obtain a breeders certificate must contain or attach, as appropriate, "… the geographical origin of the new protected varieties raw material including, if the case be, the document accrediting the legal provenance of genetic resources, issued by the National Competent Authority on access to genetic resources".

15 The UPOV Secretariat has reiterated its position opposing the inclusion of this requirement in plant breeders regimes on various occasions. This poses a problem for countries such as Peru which has ratified a Free Trade Agreements with the U.S.A. and has committed to adhering to the 1991 UPOV Act. In the case of Peru, where few applications for the protection of plant varieties have been presented and granted anyway (mainly on introduced varieties such as marigold, rice and cotton), this requirement has not been formally requested to applicants by the national IP office as yet.

16 For further details on this debate, see the article by Caillaux and Ruiz, presented at the recent XVII Inter-American Association of Intellectual Property (ASIPI) Conference, that took place in Lima, Peru in September 2009. Caillaux, Jorge, Ruiz, Manuel. 2009. Biodiversidad, Biotecnologia y Propiedad Intelectual: Algunos Retos para el Derecho, available at SPDA Information Centre (http://www.spda.org) soon part of Conference publication.

However, it was Andean Decision 391 on a Common Regime on Access to Genetic Resources (1996) that very explicitly refined and established the general principles for these requirements, which then informed processes and laws in other regions around the world. These principles can be summarized in two parts: not recognizing IP rights over innovations derived from biodiversity (genetic resources) when ABS norms are not complied with (and by extension the TK protection regulations) and raising the possibility of demanding the annulment of rights conferred and/or imposing sanctions in these cases.

At present, processes and legislation including disclosure-related provisions, have multiplied around the world, albeit not without debate and opposition.

In general terms, the practical implementation of the disclosure requirement in countries that have adopted and incorporated it in their legislation is still in its initial stages. In this context, IP authorities including patent examiners, have started to raise questions and concerns regarding some of the practical implications of the requirement.[17] Some of these concerns include questions on the type of sanction or measure to be adopted for not disclosing origin during the application procedure or once the patent is granted. There are also questions concerning which is the most appropriate moment for the authority to verify the requirement. These are only a few of the practical complexities that need additional reflection and thought and maybe legal adjustments to make disclosure operational.

Other questions that continually emerge among patent examiners in particular include:

• Is the sanction of annulment of a patent too severe – specially when a right is granted to an inventor who may have acted in good faith?

• Is annulment also too severe in that it eliminates the possibility for benefits to effectively generate and be shared?

• Can an examiner determine with absolute certainty if an invention requires an access contract or other certification?

• Would it be more convenient to seek sanctions outside the system of IP for noncompliance of this requirement (i.e. civil sanctions)?

• In which cases (which inventions) should IP authorities/ examiners demand this requirement?

• Would voluntary disclosure mechanisms be more practical?

Ultimately, the key issue is determining unequivocally when and under what circumstance (for what invention or claim) should disclosure of origin and legal provenance or the certificate of origin be required.

The Position of Some Intellectual Property Offices

Regularly over the past few years, representatives of intellectual property offices - including patent examiners - of various countries have agreed in four points:[18] First, patent office examiners oppose – or lack the capacity of – processing and reviewing more requirements than those they already evaluate as part of regular patent procedures. The possibility of undertaking additional, thorough reviews of ABS/TK related disclosure requirements (including compliance with PIC, MAT and benefit sharing), in addition

17 This is one of the conclusions of the International Workshop on the Application of Disclosure of Origin Provisions ad Legal Provenance in Intellectual Property Legislation organized by INDECOPI, WIPO, SPDA and the Initiative for the Prevention of Biopiracy, that took place in Lima on August 13-14, 2009. The report of the workshop is available at http://www.biopirateria.org

18 Patent authorities (including patent examiners) who participated in the International Workshop on the Application of Disclosure of Origin Provisions and Legal Provenance in Intellectual Property Legislation (see supra 16) included: Colombia, Brazil, Ecuador, Spain, Mexico, Peru and Switzerland. Representatives of WIPO and the academic sector of U.S.A. also participated, as well as various Peruvian experts and representatives of public and academic institutions.

to existing formal and substantial patent application and claims review, is almost, in practical terms, nonexistent. This is especially true in the case of offices in developing countries that have limited institutional capacities and personnel to undertake this work and in offices that are over burdened with applications and pending review processes (many in developed countries).

Second, examiners strongly argue for the development and recognition of a simple document or instrument (possibly a certificate of origin or legal provenance universally recognized) as a means to verify compliance with disclosure as it relates to ABS and TK. The sole existence and verification of the document by IP authorities would mean procedures have been followed. This means that no substantial, content-related analysis is made of the certificate, except where there may be a need to corroborate the veracity and legality of the document, for example through a "cross-examination" with a database.

Third, the disclosure of origin requirement is not equivalent to disclosure of legal provenance. In the case of origin, many patents, mainly those known as "naturist patents" (which refer to natural products, such as creams, dyes, oils, ointments, etc.) already include the geographical origin of the materials subject to protection, albeit sometimes in general terms. In the case of biotechnological inventions, to determine the geographical origin of a specific gene, of a group of genes, of the invention in broad terms, of a molecular structure, of the specie where the gene originates, etc. is complicated. The patent may relate to an already complex and multiple claim innovation, or be part of an equally complex process that takes place over a long period, all of which add complexity to the challenge of determining legal provenance (even origin). In both cases, a universally recognized document or certificate would rapidly allow the authority to take action. This type of document may be the subject of discussion during negotiations of the ABS International Regime and is an area where multilateral agreement is required to facilitate actions by IP authorities.

Finally, examiners also point to the importance of detailed regulations and procedural administrative mechanisms, so that certainty and security can be guaranteed for the benefit of the patent applicant and the intellectual property authority. Ultimately, this will also contribute to effectively safeguarding the rights of the countries of origin and indigenous groups, which may have specific interests vested in certain innovations.

Disclosure of Origin as Part of a System to Protect the Interests of Bisodiversity and Traditional Knowledge Holders

It is important to indicate that disclosure of origin and legal provenance are only a component of a broader and coherent ABS system where the interests of countries of origin or providers of genetic resources and their indigenous peoples are protected in an effective manner. Disclosure itself does not guarantee justice or equity. It must be complemented with operational and efficient ABS and TK protection norms, exchange of information mechanisms that articulate the actions of both IP and ABS authorities and good faith from those who access and use genetic resources and TK. Ultimately, there is a need for institutional structures and procedures that assist key actors in their actions (and capacity building efforts).

In order for a system to be effective, the following minimum requirements must be met and components considered:

- Clear and operational ABS and TK regulations,
- Clarity in laws and regulations,
- Adjustments in national laws to incorporate the requirement of disclosure (in all countries),
- A universally accepted certificate of origin or legal provenance,
- Efficient ABS information systems that facilitate exchanges between intellectual property and ABS authorities, and
- Mechanisms to monitor and assess the systems performance in general.

If a brief review were made regarding the different legal and institutional frameworks on ABS and TK that exist in the region and throughout the world, it could be rapidly verified that most of these requirements are not met and the required components are not in place. As a result, countries are facing considerable difficulties in the process of implementing their ABS and TK regulations. Institutional and legal frameworks tend to be very complex, with high transaction costs and few incentives to stimulate compliance. Limited clarity in the content of ABS and TK laws and regulations also affect their applicability. Although quite a few countries (Andean Community, Brazil, Costa Rica, Panama, etc.) have included requirements for disclosure, in practice, authorities are not fully applying

these regulations or demanding these requirements in particular. The acceptance of a universally recognized certificate of origin is still under discussion, and there is limited interaction between IP and ABS authorities, even when coordination and cooperation are required by law. Finally, a monitoring or assessment system on the operational capacity of these mechanisms does not exist.

Recommendations

Burdens generated by the requirement. The requirement for disclosure of origin or legal provenance should not impose unnecessary burdens or excessive responsibilities on IP offices, mainly patent examiners. In this regard, the possibility to have, amongst others, a universally accepted certificate of origin, a centralized online mechanism or database, and the presumption of god faith, are elements that the design and implementation of a system of thus nature should take into account to be effective and successful.

International and multilateral action. Many patent applications and patents granted indicate the geographical origin of the invention in question or its components. This is mainly the case with "naturist patents" or patents derived from biodiversity in general. In these situations, the requirement for disclosure of origin is automatically complied with. However, this is more of a practice or custom in certain sectors and not an obligation in every case. There is need for an international agreement to make disclosure of origin mandatory – with appropriate specification of what exactly origin relates to (the invention per se, its components or the specie).

Limitations of disclosure of origin. Although disclosure of geographical origin is important, it is not enough to guarantee the interests of countries or communities providing genetic resources and TK, respectively. Disclosure or indication of legal provenance adds a level of legal certainty. In this regard, the ABS International Regime may determine the need for this requirement. If TRIPS contains flexibilities in order to recognize this type of disclosure through a creative interpretation of article 29 and others, the ABS International Regime may at the same time, serve as a platform of action to encourage countries to modify their specific legislation on intellectual property and demand this requirement globally.

Disclosure as part of a system: disclosure v. certificate of origin. Disclosure and the related certificate should be understood as part of an integrated system where different components interact among themselves. The

implementation of the ABS International Regime may be the right time to determine the real possibilities for a certificate. It may also propose the progressive recognition and implementation of disclosure of origin first, and legal provenance thereafter, or establish a pilot program in some countries to evaluate its performance or application in practice. The idea of disclosure should remain "open" on the agenda in forums such as the WIPO and the WTO, and this is the responsibility of countries of origin and groups, such as the Group of Like-Minded Megadiverse Countries.

The case of microorganisms. A legal international instrument that could adapt itself, simply and rapidly, to the need for the requirement of disclosure, is the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, inasmuch as the countries agree that all deposit of microorganisms in authorized institutions must indicate at least the geographical origin as well as the legal provenance of the materials, at the specimen level even.

The UPOV System. The UPOV System, regardless of the resistance of some members and its Secretariat, should consider the requirement for disclosure in relation to the origin of the protected variety and/or its genetic components.

Information System. The success for disclosure and a possible certificate depends to a great extent on an information system that includes relevant and appropriate information for patent and ABS authorities to carry out their activities in an efficient manner. The Clearing-House Mechanism of the CBD could be the node to centralize useful information for either one or the other. The question of how would this system administrated and by whom is yet to be answered.

About the author

Manuel Ruiz Muller is Director and Principal Researcher in the International Affairs and Biodiversity Program of the Peruvian Society for Environmental Law (SPDA).

ICTSD welcomes feedback and comments on this document. These can be sent to Marie Wilke at mwilke@ictsd.ch.

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