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Policy coherence in a multi-institutional setting. The EU's policy on genetic resources in the CBD / WIPO / TRIPS nexus[1]

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The present paper aims at an analysis of the coherence of the European Union's policy output in the field of Access and Benefit-Sharing, in the nexus between the Convention on Biological Diversity, the World Intellectual Property Organization and the Agreement on Trade-related Aspects of Intellectual Property Rights. As some preliminary data suggests, during 2006, the EU approach to ABS was fundamentally reorganized. The paper sets out to test whether such a reorganization can be found at the level of policy coherence. Statistical analysis suggests, that with one of two measures for policy coherence, a rupture around 2006 can be observed.

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1. Introduction

Genetic resources have been regulated by international regimes since the 1960s, although a comprehensive system did not emerge until the beginning of the 1990s. This system currently consists of five primary regimes: the Convention on Biological Diversity (CBD), the Agreement on Trade-related Aspects of Intellectual Property Rights (WTO-TRIPS), the World Intellectual Property Organization (WIPO), the International Union for the Protection of New Varieties of Plants (UPOV) and the International Treaty on Plant Genetic Resources for Food and Agriculture (FAO – treaty). This system has famously been dubbed the "regime complex" for plant genetic resources (Raustiala and Victor 2004). It is characterized by significant functional overlaps between the basal regimes, which are, amongst themselves, not hierarchically ordered.

The term Access and Benefit-Sharing (ABS) of genetic resources refers to the way in which national states grant third parties access to genetic resources on the basis of a contract that specifies the compensation the respective state (or the respective indigenous community) receives from the third party. The current international negotiations on ABS encompass such diverse issues as a potentially mandatory disclosure of origin of genetic resources in patent applications, protection of Traditional Knowledge as well as international standards for domestic implementation clarifying access to genetic resources. An ABS protocol for the CBD is currently in the final phase of negotiation. These negotiations are generally characterized by a marked North-South divide due to fundamentally differing interests. Northern industrialized countries (especially the JUSCANZ group, that is, Japan, USA[2], Canada, Australia, New Zealand) tend towards an emphasis of Intellectual Property Rights (IPRs) in the governance of genetic resources; whereas southern actors (such as the African Union Group, the like-minded group of megadiverse countries and GRULAC), being primarily providers of genetic resources, emphasis the compensatory mechanisms entailed in benefit-sharing arrangements (Brand and Goerg 2006; Brand 2008).

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[2] The US is not an official party to the CBD, so it participates only indirectly over the JUSCANZ group.

Within this North-South divide, the European Union (EU) occupies a middle ground. Although the economic interests of the European Life-sciences and biotechnology industries are represented in the EU's policy on ABS, the European approach is nevertheless substantially based on multilateralism and a careful balancing of provider and user interests. The European Commission is currently within the lead in the EUs ABS policy, and in spite of significant divergences of interest between member states, was able to formulate a distinct and comprehensive European position.

The present paper aims at a conceptualization of the EUs behavior within the regime complex. The paper sets out to test the preliminary presumption, that during 2006, the EU approach to ABS was fundamentally reorganized, as some data suggests (i.e. Interview 1, Interview 2). After the ABS negotiations nearly broke down during the fourth session of the CBDs ABS working group (ABSWG), and after a deadline for the final negotiations being in 2010 was established at COP 8 in Curitiba, 2006, the Commission was apparently able to overcome differences of interest between member states, and put itself in the forefront of the ABS negotiations. The Commisson was able to produce (via a lengthy scientific consultation process during 2006) a number of comprehensive positions on ABS, allowing it to spearhead the European approach to the international ABS negotiations

To test this presumption, I will try to analyze the formal structure of the EUs approach under the perspective of its policy coherence. For the present case, I understand policy coherence as the degree to which a policy a) integrates disparate issues to a comprehensive whole and b) entails linking together the political approaches to different relevant forums. A low policy coherence will thus consist of diverse and disparate elements not being integrated into an overarching concept (a low "issue density", see below), and approaches to the relevant forums not being sufficiently fine-tuned to each other. High policy coherence, on the other hand, will link together the issues within a given policy field under a larger, potentially strategic, perspective; and this policy will be pursued in a coordinated manner within the different relevant forums. Whereas the existence of parallel forums allows opportunities for "forum shopping", (Drahos 2004; Helfer 2004; Alter and Meunier 2006; Helfer 2009; Baumgaertner 2010; Bled 2010; De BiËvre and Thomann 2010), regime complexity also poses substantial problems for policy-makers (Alter and

Meunier 2009). The existence of multiple, overlapping and non-hierarchically ordered forums increases the requirements for policy coherence.

The central question thus is:

RQ: how does the coherence of the EU's ABS policy change from the period 2002-2005 to 2007-2010?

The time-span to be investigated ranges from 2002 until 2010. The beginning date of 2002 was chosen since around this time, negotiations within WIPO and CBD took off, with WIPO's Intergovernmental Committee on Genetic resources, Traditional Knowledge and Folklore (IGC), and the ABSWG of the CBD taking up work. For this period, I will focus on CBD, WIPO and TRIPS. I will exclude UPOV since Plant Variety Protection is not a central issue in the current ABS negotiations; and I will exclude the FAO-treaty due to its limited scope. Empirically, I will analyze the EU's submissions, position papers and available session protocols for the negotiations within WIPO / CBD / TRIPS. I will exclude from the corpus those passages of documents that do not bear direct relevance on ABS. The time span of 2002 until 2010 will be subdivided into two distinct phases, 2002 until 2005, and 2007 until 2010. This is due to the presumption that the European approach to ABS was fundamentally reorganized during 2006. Thus, what this paper seeks to test is, whether the EU's submissions for the periods of 2002 – 2005 and 2007-2010 belong, in fact, to the same population, or whether differences between those can be observed. This question shall be tackled by using ANOVAs.

First, I will measure the levels of issue density for both periods. I consider those micro-elements that constitute a political position as such issues. E.g., the overall EU approach to ABS is based on the issues "disclosure of origin of genetic resources", "international access standards" etc. The numerical distribution of those issues over a population of the EU's submissions, position papers and session protocols (the "issue density") can give a hint as to how well the disparate micro-elements constituting the

European policy on ABS are brought together. A rise in issue density would imply that overall policy becomes more coherent. A low issue density, on the other hand, refers to a more or less eclectic distribution of different issues over the whole population of submissions, position papers and session protocols. This leads to hypothesis 1:

H1: the post-2006 issue density is higher than the pre-2006 level

Secondly, I will analyze to what extent the submissions to the different forums (CBD, WIPO, TRIPS) are linked to each other. A prerequisite for policy coherence in this case is that the submissions to a given forum are coordinated with the submissions to the other forums. A highly coherent policy should be expected to systematically create links between the relevant international forums. As a proxy for this linkage, I will measure the amount of cross-referencing within the submission's to a target regime to submissions made to other two regimes. Hypothesis 2 thus states:

H2: cross-referencing within the EU's submissions should be expected to be higher after 2006 than before 2006.

I will proceed in several steps. Part 2 will give a short overview over the field of ABS and the regime complex for genetic resources. Part 3 will elaborate on the European Union's (EU) external policy on ABS. Part 4 will investigate the issue density of the EU's submissions, while part 5 will look at the aforementioned cross-referencing. Part 6 will conclude.

2. The international governance of Access and Benefit-Sharing

Genetic resources are used in a multitude of products today, be they medicinal, cosmetic or agricultural. Biotechnology today is a major industry, with revenues exceeding $25 billion in 2001 in the US alone. The European biotech industry is significantly smaller, with revenues totaling $7.5 billion, and employing 34.000 people (also in 2001) (Ernst and Young 2002). Governance of genetic resources on the international level began in the 1960s, primarily by setting and clarifying intellectual property rights (IPRs). Through IPRs, ownership of a given genetic code is clarified. In genetic resources, the most common IPR is the patent. The first patent on a life form was granted in the US in 1980s after the *Diamond vs. Chakrabarty* case, and the development of modern biotechnology and its conflict lines have since been inextricably linked to the global patent system (Williams 2000).

Within the dominant, western patent systems, life forms or "essentially biological processes" are not directly patentable. In those patent systems that conform to the TRIPS standard, plants and animals *can* be excluded from patentability; whereas plant varieties *must* be made subject to some other form of IPRs, e.g. through the Plant Variety Protection offered by UPOV. What is usually patentable, on the other hand, are processes for isolating components of a life form, products that are derived from a certain DNA code, or "microbiological processes[3]" (Restaino 2002; Schertenleib 2004).

A significant North-South conflict exists in the governance of genetic resources. The geographic distribution of patents in biotechnology is geographically skewed. In 1999, industrialized countries held 97% of global patents in biotechnology (Castle 2009). Southern actors often make accusations of "biopiracy" to northern biotech firms, claiming "unauthorized commercial use of biological resources and / or associated traditional knowledge" (Mgbeoji 2006). The core of the problem consists of northern corporations acquiring genetic resources from southern countries and patenting them in the US, the EU or Japan, possibly circumventing national

[3] What the term "microbiological processes" entails concretely, is a matter of debate. Within the TRIPS council, the dominant perspective seems to be that a strict definition is even, in fact, undesirable.

regulations in the country of origin, and possibly being granted a patent on an application that might be in use by indigenous communities for quite a long time Dronamjaru makes the accusation that Northern appropriation of genetic resources "presents itself as a respectable business, utilizing the legal terminology of patents, which were specially created for a subtle and smooth robbery under the cloak of legality" (Dronamraju 2008). Thus it is primarily the question of patentability that determines the North-South conflict in genetic resources; and which leads to the respective international institutions being "contested regimes" (Brand and Goerg 2006; Brand 2008).

The present system governing genetic resources took shape at the beginning of the 1990s with two significant events. First, the Convention on Biodiversity (CBD), founded in 1992, aimed at the conservation, sustainable use, and equitable sharing of benefits arising out of genetic resources. The CBD is generally considered as an agreement dominated by Southern interests (Rosendal 2006). Its origin can be traced back to North-South conflicts in genetic resources arising in the 1980s, when northern biotechnology corporations were acquiring and patenting southern genetic resources (which were then considered as the "common heritage of mankind") on a large scale (Raustiala and Victor 2004). During the Rio Summit, Southern actors succeeded in establishing a framework which would allow them to participate in the profits made by Northern biotechnology corporations; to regulate the conditions under which northern actors are granted access to genetic resources; to prevent ongoing large-scale loss of biodiversity; and to see to a sustainable use of genetic resources.

To achieve this triple goal, the CBD made use of Access- and Benefit-Sharing (ABS). ABS is based on the principal national ownership of genetic resources occurring on a given territory. Access to genetic resources should, in accordance with the CBD, only be obtained from competent national authorities under two conditions. First, that the respective authority is informed beforehand on which specific resource is obtained, in which context and to what end. The acceptance by a nation state of a private party obtaining a resource under these conditions is called Prior Informed Consent (PIC). Secondly, the sharing of (monetary or non-monetary) benefits arising out of the (commercial) utilization of a resource is negotiated between the accessing party and the national authority on Mutually Agreed Terms (MAT), that is, in the form of a contract.

Generally, the impact of the CBD on national legislation has been limited. The CBD, and especially the later "Bonn guidelines", were to provide model legislation for national states to implement as domestic ABS frameworks. This has happened in a limited number of countries (in the Andean region, India, Australia, Japan), but a widespread impact of the CBD can currently not be witnessed. Currently ongoing are the negotiations for a protocol to the CBD, which is to further specify and regulate ABS, maybe even with binding components. These negotiations are to be concluded in October 2010.

The second regime governing genetic resources emerging at the beginning of the 1990s was the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) as a part of the World Trade Organization (WTO). Through TRIPS, minimal standards for governing Intellectual Property Rights (IPRs) worldwide were set, with implementation being mandatory for WTO members. While not specifically geared towards genetic resources, TRIPS foresees a general patentability of genetic resources. Of special interest here is Art. 27.3, which has been strongly contested and is up for review in the TRIPS council since 1999. According to Art. 27.3, micro-organisms, non-biological and microbiological processes are deemed patentable substance matter; while plants, animals and "essentially biological processes" are not to be patented. Some parties to the TRIPS agreement such as members of the African Group are fiercely opposed to any possibility of patenting life forms; but due to the resistance of Northern states, a substantial revision of Art. 27.3 is highly unlikely. Currently, progress in TRIPS is slow due to the lacking political dynamic of the Doha round.

A fundamental asymmetry between CBD and TRIPS exists in their respective legal character. Where the CBD is currently a soft-law agreement without substantial enforcement mechanisms, parties to TRIPS can make use of the powerful Dispute Settlement Mechanism (DSM) of the WTO for ensuring compliance. This asymmetry also implies that, while access to genetic resources via IPRs can easily be obtained in the context of TRIPS, a corresponding mechanism for benefit-sharing does not have the same kind of legal authority.

Interpretations over the relationship between CBD and TRIPS differ significantly. Whereas Northern states generally contend that there is no contradiction, some

Southern states hold that the provisions of the two are in conflict, and that TRIPS should be brought in line with the CBD.

The third regime relevant in this context is the World Intellectual Property Organization (WIPO) of the UN. In general IPR regulation, it has become quite marginalized by TRIPS, since the latter can build on the DSM of the WTO to enforce compliance; in fact, one of the reasons for Northern states for founding TRIPS were enforcement problems under WIPO. WIPO governs a host of different treaties relevant to IPRs. In the context of genetic resources, these are: the Patent Law Treaty (PLT), the Patent Cooperation Treaty (PCT) and the proposed Substantive Patent Law Treaty (SPLT), aiming at harmonizing IPRs on a global scale even beyond the requirements of TRIPS. A consultation process regarding genetic resources and Traditional Knowledge has been ongoing in WIPO's Intergovernmental Committee (IGC) since 2003. In the context of this negotiation process, participants aim at the creation of an international regime / mechanism for the protection of Traditional Knowledge / Traditional Cultural Expressions and genetic resources. Negotiations within the IGC received a boost when the IGC's mandate was renewed in 2009, with the aim of entering "text-based negotiations" in 2010. The creation of an international regime for protection of TK is envisaged in 2011.

3. The EU's external policy on Access and Benefit-Sharing

The European Union has not developed a comprehensive internal framework for ABS, although some member states have passed legislation on their own. The focus of this work will be on the *external* ABS policy of the EU, that is, its policies towards the primary regimes regulating ABS on the international level.

Until 2006, the EU's position on ABS was more or less fragmented. During that period, member states believed that problems related to ABS and genetic resources could be resolved via a sole recourse to IPRs. Member states' preferences were also diverging significantly; while those countries with a strong pharmaceutics industry (France, Britain, Germany, Italy) did not look to kindly on the compensatory

mechanisms of the CBD, other countries were more oriented towards a developmental position accommodating the interests of the global South (Interview 1).

In January 2006, the talks within ABSWG 4 stalled. At COP8, taking place in March 2006 in Curitiba, parties to the CBD agreed to set in place a deadline for finalizing the International Regime by 2010. Although the EU supported this decision, it nevertheless meant that internal coordination had to be intensified.

Since about 2006, the EU possesses a more diversified external approach for ABS, which is being negotiated in TRIPS, WIPO and CBD simultaneously, the focus being of course the International Regime on ABS of the CBD. The Commission managed to put itself in the leading position; substantially drawing on epistemic communities, during 2006, the Commission was able to formulate a coherent and encompassing European policy on ABS, which the member states followed (Interview 1). The Commission also managed to propel itself onto center stage in the negotiations; in TRIPS and in the CBD, the Commission is the sole representative of the EU.

The EU policy is here based on a multidimensional, multilateral approach. The model that the EU proposes is built upon several central components. First, the EU wishes to develop "international access standards" as a model legislation for other countries to adapt. International Access Standards, mentioned first at ABSWG 6, would provide guidelines for third parties to base their domestic ABS frameworks on. They would include measures to facilitate legal procedures between users and providers of genetic resources; access to resources for non-commercial purposes is to be facilitated; and whether additional compliance measures are appropriate in case of breach of a domestic ABS framework is to depend on whether this framework is in conformity with the international access standards. Thus compliance measures are directly linked to whether a party implements the international access standards. The rationale behind this is that it is difficult to enforce compliance under conditions of legal uncertainty. The standards would not require a harmonization of national laws and administrative procedures; but a mechanism is to be in place to monitor whether national regulations are in accordance with the access standards (CBD ABSWG 6 2008).

Secondly, the EU ponders the possibility of enforcing compliance with domestic ABS frameworks and PIC through disclosure of origin of the respective genetic resource. This means that an applicant for a patent on a certain resource would have to provide

documentary evidence on the whereabouts of his resource, thus checking compliance with domestic ABS frameworks and PIC. An international system is to be established which allows provider countries to globally track patent applications which make use of genetic resources found on their territory. Still, non-compliance with this requirement is not to negatively influence patentability, but should rather be a matter to be treated within civil law or via administrative procedures (i.e. fees); the granting of a patent should not be linked to whether a party complies with the disclosure requirement.

Thirdly, the EU seems to be especially concerned with "misappropriation" of genetic resources, or what is being called "biopiracy". Misappropriation is conceived of as acquiring a genetic resource in violation of the respective domestic ABS framework, that is, without PIC or in violation of MAT. The International Regime shall also apply to subsequent uses by an other party of misappropriated material. Users are to apply preventive measures as to ensure they are not using a pirated resource; measures against misappropriation shall also apply, if users fail to take these preventive steps. Sanctions against misappropriation shall be determined on the domestic level. Also, the EU distinguishes "misappropriation" from "misuse", the latter constituting a breach of the MAT contract, an act which can already be persecuted under other international treaties.

Thus, although no common internal ABS legislation exists, the EU has developed a diversified and comprehensive external governance model for ABS which is being pursued in three forums simultaneously. That the EU is in fact engaging in these three forums (CBD, WIPO, TRIPS) at the same time hints at the EU external governance model for ABS being the result of a substantial political compromise. In contradistinction, the US pursues its ABS policy primarily within TRIPS and, partially, within WIPO, thus displaying an approach to genetic resources primarily based on strong IPRs while neglecting the compensatory dimension. The European governance model for ABS, on the other hand, seems to be based on a fundamental compromise between northern interests in strengthening the biotechnological industry, and southern interests in compensatory arrangements. Thus, developmental, environmental and trade interests overlap.

There are several reasons for this accommodating EU approach. First, the European biotech industry is distributed in an asymmetrical geographic way, which implies that not all countries have an interest in strengthening the respective industry through strong IPRs (Strasser and Redl 2010). Second, as far as the developmental aspect of ABS is concerned, the EU is globally the biggest donor of developmental aid, and houses three of the four "G0.7" countries, which have lived up to their promise of donoring 0.7 percent of GDP for developmental aid (Rabe 2003). Third, the EU understands its role in world politics as substantially multilateral and consensus-based, which might also play a role for accommodating the positions of the global south.

The EU envisages a functional division of labor between TRIPS, WIPO and CBD. Issues of Traditional Knowledge are to be strictly WIPO's territory. The relationship between CBD and TRIPS is a further area of concern and it has long been on the agenda of the TRIPS council. The EU's official position is, of course, that there is no conflict between the two regimes, arguing that state sovereignty over genetic resources does not preclude patenting; and patenting does not preclude benefit-sharing arrangements. Still, the EU holds that the two regimes should be more fine-tuned to each other. The EU considers disclosure of origin of genetic resources a crucial feature that would provide an "interface" between CBD and TRIPS. Through a potentially global disclosure system, the IPR system could be strengthened and compliance with benefit-sharing arrangements under the CBD be facilitated.

4. Issue density in the EU's submissions

The respective coherence of the pre- and post-2006 output will here be measured via an ANOVA – based comparison of means of issue density. The analysis has to take into account the nature of the EU's submissions, position papers and session protocols. In international negotiations, communication equals the pursuit of interests, that is, saying is doing. Without unambiguous communication with the negotiation partners, the attainment of policy goals becomes difficult. This leads me to the assumption, that the written and spoken communications of the EU are in a close fit

with the EU's actual preferences, which in turn allows to deduct (in)coherence of actual policy from the (in)coherence of communications.

A rise in the level of policy coherence could theoretically have two reasons. First, as is hypothesized here, policy might become fundamentally reorganized, thus leading to a "leap" in the level of coherence. We might also expect policy coherence to be correlated to the time spent within negotiations; in this perspective, an actor would develop its position further and further as negotiations progress, in a gradual fashion. I will return to this point below.

Under "issue" I understand single political positions within a larger policy field. The sum of issues constitutes the political position of an actor. I understand the notion of "issues" in a formal rather than a substantial way. E.g., the issue "disclosure of origin of genetic resources" can take on several values, i.e. "disclosure should be a requirement for patentability" or "disclosure should not impact on patentability". Here, it does not matter, what concrete values these variables assume; what is of relevance, instead, is how they are brought together within submissions.

For the governance of ABS, I identified a total of 5 relevant issues. These are strengthening of procedures for Mutually Agreed Terms (MAT) possibly with the use of Material Transfer Agreements (MTAs); strengthening of Prior Informed Consent (PIC); Compliance measures; measures against misappropriation of genetic resources; and Disclosure of origin. These all occur over the whole time period under consideration. In 2006 / 2007, the issue of "international access standards" was created but not factored in so as not do distort the comparison.

The sample was drawn from protocols of negotiations from and submissions to WIPO, CBD and TRIPS. From these, only those parts that contained spoken or written text by the EU, were selected; this selection was then reduced to those documents bearing relevance on ABS. A total of 27 documents thus made up the sample; 18 from 2002-2005, 9 from 2007-2010. Testing the two samples for differences with ANOVA resulted in a statistically significant difference at the $p = 0.022$ significance level. Whereas submissions in the 2002-2005 period had a mean score of 1,85 issues, this number rose to 3.38 in the latter period. Standard deviations were almost identical for both periods, with 1,31 and 1,32 respectively. Thus the

relative distribution of issues stayed relatively constant, while only the mean score increased.

Instead of assuming a structural break in 2006, we have to include the possibility of a learning process leading to linear growth over time: an alternative explanation for differences between pre- and post-2006 levels would be, that, as negotiations proceed, political positions become gradually refined by better linking together the disparate elements within the ABS field. This explanation would oppose the idea of a "leap" during 2006; instead, we should witness a constant growth from 2002 until 2010.

In order to test this alternative explanation, it was tested how good linear, quadratic and cubic regression account for variance. With R-squared levels of 0.287 and 0.31, these 2nd and 3rd order regressions gave a better explanation than the linear regression (r-squared value of 0.216). This might be a cautious hint at issue density, indeed, taking a leap around 2006, but the small n-numbers preclude any quick jumping to conclusions.

5. Cross-referencing in the EU's submissions

As mentioned, the existence of parallel regimes within a policy area increases the requirement for linking together the policies towards the different singular regimes. In this respect, coherence refers to the degree to which the policy towards a given regime takes into account the policies towards the other regimes within the complex. This inter-institutional coordination of policies between WIPO, CBD and TRIPS shall here be measured by the degree, to which a submission to a regime A refers to submissions to regimes B and C. Cross-referencing between submissions is here regarded as a measure, of how well the cross-institutional policies are linked.

Still, the result of the ANOVA is, that with $p = 0.3$, the difference in means between the pre- and post-2006 phase is not significant. Further, the mean score of cross-referencing between submissions goes down from 0.63 in the first period, to 0.38 in the second, although, with a p value that high, the relevance of this decrease in mean scores is questionable.

6. Conclusion

The paper aimed at measuring the development of the coherence of the EU's submissions, position papers and session protocols to three international forums, taking issue density and cross-referencing as proxies for coherence. The paper set out to test, whether, as some data suggested, the qualitative reorientation of the EU's policy on ABS in 2006 was reflected in the coherence of its submissions, leading to a leap in coherence levels during 2006.

While issue density was higher post-2006 than before, the data suggests that this is not due to a linear increase. In light of the small n-numbers, caution in the interpretation of the results would be appropriate, but there are some hints, that issue density as a measure of policy coherence leaped during 2006. This would, indeed, hint at the coherence of the EU's ABS policy becoming reorganized during 2006

The second measure of coherence, cross-referencing between submissions, showed no statistically significant difference between the pre- and post-2006 phase, neither in the form of a gradual increase or a rupture, although the mean score halved. This result is out of line with the initial assumptions. Two possible explanations are in line, the first being that the decrease over time is rather due to chance, potentially resulting from small n-numbers. Secondly, since there seems to be no plausible reason why the development of the EU's ABS policy should lead to a decrease in cross-referencing, the question is in order whether cross-referencing is actually a potent measure of coherence.

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