# Speech 1NC Loyola Rd 3 vs Dulles 9-4 4PM

## 1

#### Interp – the aff must have a delineated definition of exclusivity in the 1AC.

#### Exclusivity is flexible and has too many interps – normal means shows no consensus and makes the round irresolvable since the judge doesn’t know how to compare between types of offense and OW since it’s a side constraint on decision making.

Hennebry PhD 18 [Sarah Hennebry (BA, BSc (Hons), PhD, MIP Law). “When a 20 year patent term just isn't enough: Market and data exclusivity”. FPA Patent Attorneys. 2018-01-31. Accessed 8/31/21. <https://www.fpapatents.com/resource?id=483> //Xu]

In the US, “exclusivity” provided by the Food and Drug Administration (FDA) generally refers to market exclusivity only, but may also have the effect of providing a period of data exclusivity. (a) Exclusivity for new chemical entity (NCE) – small molecules Up to 5 years of exclusivity are granted by the FDA in respect of a pharmaceutical product that contains an active moiety that has not previously been approved by the FDA. The period of exclusivity commences on the date of the NDA (New Drug Application) approval. The NCE Exclusivity provisions prohibit the FDA from accepting for review during the period of exclusivity, any ANDA (Abbreviated New Drug Application) or application under s 505(b)(2) for a drug containing the same active moiety. (Ostensibly, this is a prohibition on the acceptance of any application for regulatory approval for a generic product, or any application that relies upon data that has not been obtained or provided by the applicant). The period of exclusivity is: 4 years if an ANDA or s 505(b)(2) application contains a certification that any patent relevant to the pharmaceutical product is invalid or is not infringed by the generic product; or 5 years if an ANDA or s 505(b)(2) application does not contain a certification that any patent relevant to the pharmaceutical product is invalid or is not infringed by the generic product (b) Orphan Drug Exclusivity (ODE) A period of 7 years of market exclusivity is provided by the FDA in respect of pharmaceuticals that are designated and approved to treat diseases or conditions affecting fewer than 200,000 individuals in the US (or more than 200,000 and no hope of recovering costs). The period of exclusivity commences on the date of approval of the NDA (New Drug Application) or BLA (Biologics Licence Application). Orphan Drug Exclusivity prevents the FDA from approving any other application for the same drug for the same orphan disease or condition. (This includes any ANDA, any s 505(b)(2) application or any “full” NDA or BLA). (c) “Other” Exclusivity (New clinical investigation) A three year period of exclusivity may be granted in respect of a pharmaceutical product for which regulatory approval was obtained, where the FDA had previously provided regulatory approval of another pharmaceutical product containing the same active moiety. (In other words, a shorted period of three years exclusivity is provided where the NDA does not relate to a new chemical entity, including where approval is required for a new indication, where the NDA relates to a combination product, or where approval is required for a change in the pharmaceutical product). A three year exclusivity period is granted by the FDA when an application or supplement contains reports of new clinical investigations (other than bioavailability) conducted or sponsored by the applicant. During the three year period of exclusivity, the FDA must not approve any ANDA or s 505(b)(2) application that relies on the information provided to the FDA supporting the approval of the pharmaceutical product. (d) Exclusivity for paediatric indications An additional 6 month period of exclusivity is provided when the sponsor of a drug conducted and submitted pediatric studies on the active moiety in response to a Written Request from the FDA. The 6 month period of Pediatric exclusivity can attach to any of the NCE, ODE or “Other” exclusivity periods identified items a) to c) above, and to the period at item g) below. The additional 6 months period of market protection attaches to period of existing exclusivity, but in addition, to the term of all existing patents relevant to the active moiety in the product. (e) Generating Antibiotic Incentives Now (GAIN) Exclusivity An additional 5 year period of exclusivity is provided by the FDA for products that are granted a QIDP (Qualified Infectious Disease Product) designation. (f) First generic exclusivity (180-day Exclusivity) A period of exclusivity is also provided by the FDA the first applicant of an ANDA for approval of a generic pharmaceutical product. A company may seek approval, under certain provisions under US law, to market a generic drug before the expiration of a patent relating to the innovator drug. The first company to submit an ANDA to the FDA has the exclusive right to market the generic drug for 180 days. The 180-day exclusivity provisions provides an incentive of 180 market exclusivity for the first generic applicant who challenges a listed patent. For example by filing a paragraph IV certification in the ANDA) or runs the risk of having to defend a patent infringement suit. The 180 day period of exclusivity commences on the day that the commercial marketing of the first generic product begins, or from the date that a court find a relevant patent invalid, unenforceable or not infringed (whichever date is earliest). (g) Exclusivity for biologics: Reference product exclusivity Reference product exclusivity is the period of time during which a biosimilar applicant (ie a sponsor submitting a 351(k) application) is not permitted to submit and the FDA is not permitted to license a 351(k) application that refers to a reference product. A reference product is deemed to be the single biological product licensed by the FDA (under section 351(a) of the PGS Act), under which a proposed biological product is evaluated in a biosimilar application (a 351(k) application). The period of exclusivity extends from the date of first licensure of the reference product. Approval of a 351(k) application may not be made by the FDA until 12 years from the first licensure of the reference product (plus any additional 6 month period for pediatric indication). A 351(k) application may not be submitted to the FDA for review until 4 years after the date of first licensure. For more detailed information on exclusivity provisions in the US, please see the following: USFDA Note on Patents and Exclusivity USFDA FAQ Patents & Exclusivity USFDA Draft Guidance for Industry Product Exclusivity Biological Products

#### Violation – you don’t – exclusivity matters for Evergreening – Feldman 3 references exclusivity.

#### Prefer –

#### 1] Stable Advocacy – they can redefine in the 1AR to wriggle out of DA’s which kills high-quality engagement and becomes two ships passing in the night – triggers presumption since the aff wasn’t subject to well researched scrutiny. We lose access to nuclear deterrence DA’s, Innovation DA’s, basic case turns, and core process counter plans that have different definitions and 1NC pre-round prep.

#### 2] Ground – not defining hurts my strategy since they can shift out as I ask DA questions, so I err on the side of caution and read generics which get destroyed by AC frontlines.

#### 3] Real World – policy makers will always define the entity that they are prohibiting. It also means zero solvency, absent spec, actors circumvent since there’s no specific object of the plan and means their solvency can’t actualize.

#### Espec isn’t regressive or arbitrary – its core topic lit for what happens when the aff is implemented and cannot be discounted from prohibition policies that require enforcement to function.

## 2

#### Interp debaters may not start the claim that contradictions affirm

#### Violation they did

#### Infinite abuse

#### Topic ed

## 3

#### Interp: Debaters must send speech docs in PDF format.

#### Violation – they use Word

#### Prefer –

#### 1] PDFs are better for file exchanges – you don’t know how [your computer/Gmail filter/speechdrop/etc] could’ve changed the format of the docs which means all their arguments are suspect and precedes your offense.

Solid Documents ND [Solid Documents. “PDF vs DOC: When to Use Each”. No Date. Accessed 7/2/21. <https://www.soliddocuments.com/pdf/_word_format/170/1?id=170&tag=1> //Xu]

File Exchange: PDF is ideal for document exchange between users. Not only is it a compact format, but it can also store metrics and information about its own appearance (layout, fonts, content, color, etc.) within the document itself. This means that it may not have to rely on the fonts and settings that may or may not be installed on a user’s computer to display properly.

#### 2] Inclusion – not everyone has access to Word licenses, which often costs hundreds of dollars and excludes low resource debaters which o/w cuz it’s a litmus test to determining whether you are accessible and is an impact multiplier for other voters

Solid Documents 2 [Solid Documents. “PDF vs DOC: When to Use Each”. No Date. Accessed 7/2/21. <https://www.soliddocuments.com/pdf/_word_format/170/1?id=170&tag=1> //Xu]

Anyone Can View It: To view a Word document, you must have proprietary software (Microsoft® Office) installed on your computer. On the other hand, a PDF can be viewed by anyone who has the free Adobe® Acrobat® Reader, which is easy to download and which comes standard on many computers running Windows operating systems. This makes PDF the preferred format for creating a document that many can view.

#### Fairness – its constitutive to debate as competitive activity that requires objective evaluation

#### Education – it’s the only portable impact to debate

#### CI – a) brightlines are arbitrary and self-serving which doesn’t set good norms b) it collapses since weighing between brightlines rely on offense defense

#### Neg theory is drop the debater – a) Prep skew – aff’s infinite prep means they can frontline every shell marginally enough to be efficient at DA and skew substance enough to deflate theory and win b) 1AR Flex – It’s key to check 1ar flexibility since you can moot all 6 min of my offense and restart the debate on unpredictable layers while kicking the arguments that were abusive.

#### No rvi

#### [a] Baiting—they’ll bait the theory debate and prep it out—justifies infinite abuse since they’ll get away with unacceptable practices every time.

#### [b] 1AR all-outs—they’ll collapse entirely to theory which crowds out substance and kills education.

#### [c] Chilling effect—people will be scared to read theory since they can lose off of it, so no one will check abuse.

#### [d] Norm-setting—I shouldn’t be forced to keep advocating for a bad norm if I realize it’s bad in the middle of the round. Then bad norms would be spread.

#### [e] Flex—RVIs make theory uncondo so I always have to go for that route to the ballot, but both debaters should get multiple relevant layers and collapse options. Otherwise tiny mistakes cost me the debate which isn’t a holistic test of skill.

#### [f] Illogical—doesn’t make sense to win just for being fair.

#### Neg abuse outweighs Aff abuse – 1] Infinite prep time before round to frontline 2] 2AR judge psychology and 1st and last speech 3] Infinite perms and uplayering in the 1AR.

#### 1NC theory first - 1] Abuse was self-inflicted- They started the chain of abuse and forced me down this strategy 2] Norming- We have more speeches to norm over whether it’s a good idea since the shell was read earlier

#### No new 1ar theory paradigm issues- A] the 1NC has already occurred with current paradigm issues in mind so new 1ar paradigms moot any theoretical offense B] introducing them in the aff allows for them to be more rigorously tested which o/w’s on time frame since we can set higher quality norms.

#### Evaluate 1AR Voting issues after the 2NR- It’s key to reciprocity since it means we both get 1 speech each instead of them getting a 2ar to blow them up

## 4

#### The ROB is to determine the truth of falsity of the resolution –

#### 1] Textuality – five dictionaries[[1]](#footnote-1) define to negate as to deny the truth of and affirm[[2]](#footnote-2) as to prove true.

#### That OW –

#### a] Jurisdiction – judges are constrained through their constitutive purpose and proves it’s a side constraint on what arguments they can vote on.

#### b] Predictability – people base prep off the pregiven terms in the resolution.

#### 2] Isomorphism – alternative ROBs aren’t binary truth/false because of topic lit biases which increases intervention and takes the debate out of the hands of debaters.

#### 3] Inclusion – any offense functions under it as long as debaters implicate their positions to prove the truth or falsity of the resolution which maximizes substantive clash through ground and is a sequencing question for engaging in debate.

#### 4] Logic – any statement relies on a conception of truth to function – for example, I’m hungry is the same as its true that I’m hungry – logic is a litmus test for any argument and proves your ROB collapse since it relies on truth.

#### 5] reject 1AR ROBs – strat skew and shiftiness

#### Presumption and permissibility negates – a) more often false than true since I can prove something false in infinite ways b) real world policies require positive justification before being adopted – there’s alwahys an institutional DA to going through Congress c) ought[[3]](#footnote-3) means “moral obligation” so the lack of that obligation means the aff hasn’t fulfilled their burden

#### Negate –

#### 1] member[[4]](#footnote-4) is “a part or organ of the body, especially a limb” but an organ can’t have obligations

#### 2] of[[5]](#footnote-5) is to “expressing an age” but the rez doesn’t delineate a length of time

#### 3] the[[6]](#footnote-6) is “denoting a disease or affliction” but the WTO isn’t a disease

#### 4] to[[7]](#footnote-7) is to “expressing motion in the direction of (a particular location)” but the rez doesn’t have a location

#### 5] reduce[[8]](#footnote-8) is to “(of a person) lose weight, typically by dieting” but IP doesn’t have a body to lose weight.

#### 6] for[[9]](#footnote-9) is “in place of” but medicines aren’t replacing IP.

#### 7] medicine[[10]](#footnote-10) is “(especially among some North American Indian peoples) a spell, charm, or fetish believed to have healing, protective, or other power” but you can’t have IP for a spell.

#### 8] patent protection is distinct from data exclusivity.

Hennebry PhD 18 [Sarah Hennebry (BA, BSc (Hons), PhD, MIP Law). “When a 20 year patent term just isn't enough: Market and data exclusivity”. FPA Patent Attorneys. 2018-01-31. Accessed 8/31/21. <https://www.fpapatents.com/resource?id=483> //Xu]

Data exclusivity is separate from other forms of intellectual property protection, such as the protection provided by patents. In some instances, the period of data exclusivity may extend beyond the term of any patent which protects the same product.

#### That makes their plan text incoherent – the plan says “one-and-done approach for patent protection” but

Feldman 3 says Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

I believe that one period of protection **should be enough**. We should make the legal changes necessary to prevent companies **from building patent walls** and piling up mountains of rights. This could be accomplished **by a “one-and-done” approach** for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but **not all of the above** and more. Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through **legislative changes to the FDA’s drug approval system**, and would apply to patents granted going forward. One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing patent obviousness doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented. Either by congressional clarification or judicial interpretation, many pile-on patents could be eliminated with a ruling that the core concept of the additional patent is nothing more than the original formulation. Anything else is merely an obvious adaptation of the core invention, modified with existing technology. As such, the patent would fail for being perfectly obvious. Even without congressional action, a more vigorous and robust application of the existing obviousness doctrine could significantly improve the problem of piled-up patents and patent walls. Pharmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another. This behavior lets drug companies keep competitors out of the market and beat them back when they get there. We shouldn’t be surprised at this. Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results. If we want to change the system, we must change the incentives driving the system. And right now, the incentives for creating patent walls are just too great.

1. <http://dictionary.reference.com/browse/negate>, <http://www.merriam-webster.com/dictionary/negate>, <http://www.thefreedictionary.com/negate>, <http://www.vocabulary.com/dictionary/negate>, <http://www.oxforddictionaries.com/definition/english/negate> [↑](#footnote-ref-1)
2. *Dictionary.com – maintain as true, Merriam Webster – to say that something is true, Vocabulary.com – to affirm something is to confirm that it is true, Oxford dictionaries – accept the validity of, Thefreedictionary – assert to be true* [↑](#footnote-ref-2)
3. https://www.merriam-webster.com/dictionary/ought [↑](#footnote-ref-3)
4. https://www.google.com/search?q=member+definition&rlz=1C1CHBF\_enUS877US877&oq=member+definition&aqs=chrome.0.69i59j69i60l3.1863j0j7&sourceid=chrome&ie=UTF-8 [↑](#footnote-ref-4)
5. https://www.google.com/search?q=of+definition&rlz=1C1CHBF\_enUS877US877&oq=of+definition&aqs=chrome.0.69i59j69i61l3.1473j0j7&sourceid=chrome&ie=UTF-8 [↑](#footnote-ref-5)
6. https://www.google.com/search?q=the+definition&rlz=1C1CHBF\_enUS877US877&oq=the+definition&aqs=chrome..69i57j69i64j69i61j69i60l2.1976j0j7&sourceid=chrome&ie=UTF-8 [↑](#footnote-ref-6)
7. https://www.google.com/search?q=to+definition&rlz=1C1CHBF\_enUS877US877&oq=to+definition&aqs=chrome..69i57j69i60l3.1415j0j7&sourceid=chrome&ie=UTF-8 [↑](#footnote-ref-7)
8. https://www.google.com/search?q=reduce+definition&rlz=1C1CHBF\_enUS877US877&sxsrf=AOaemvI3lZsbmnXg5WHeL4m6rYGn8Vf6Aw%3A1630610232638&ei=OCMxYbCaJpO0tQb6wpGoCA&oq=reduce+definition&gs\_lcp=Cgdnd3Mtd2l6EAMyCQgjECcQRhD5ATIECAAQQzIECAAQQzIFCAAQgAQyBQgAEIAEMgUIABCABDIFCAAQgAQyBQgAEIAEMgUIABCABDIFCAAQgAQ6BwgAEEcQsAM6BwgAELADEEM6BwgjEOoCECc6BAgjECc6BQgAEJECOhEILhCABBCxAxCDARDHARDRAzoKCAAQsQMQgwEQQzoHCAAQsQMQQzoICAAQgAQQsQM6CAgAELEDEIMBOgoIABCABBCHAhAUSgQIQRgAUMLMBFjS3QRgnt8EaAJwAngDgAG2A4gB-heSAQozLjExLjEuMi4xmAEAoAEBsAEKyAEKwAEB&sclient=gws-wiz&ved=0ahUKEwiwlru9gOHyAhUTWs0KHXphBIUQ4dUDCA8&uact=5 [↑](#footnote-ref-8)
9. https://www.merriam-webster.com/dictionary/for#:~:text=English%20Language%20Learners%20Definition%20of,meant%20to%20be%20used%20with [↑](#footnote-ref-9)
10. https://www.google.com/search?q=medicine+definition&rlz=1C1CHBF\_enUS877US877&oq=medicine+definition&aqs=chrome.0.69i59.2986j0j7&sourceid=chrome&ie=UTF-8 [↑](#footnote-ref-10)