Non-voluntary use of patents for drugs to treat the Hepatitis C Virus in the United States: Mechanisms available to the Federal Government, State Governments and Private Actors

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This is briefing note setting out possible mechanisms to overcome the exclusive rights of patents for drugs to treat the Hepatitis C Virus (HCV), in the United States.

Each approach involves leadership from different actors. Each has advantages and disadvantages, including legal and practical risks.

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1. The Federal Government use of HCV patents, without permission from right holder

The first mechanism is for the United States to use its rights under 28 USC 1498(a), which reads in part:

> **28 U.S.C. 1498. Patent and copyright cases**
>
> (a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.

And, for clarity, the statute also says:

> For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

Sometimes referred to as a “government use” right, this statute allows federal agencies and third-party government contractors to manufacture and/or use any invention without authorization from the patent holder. The federal government’s rights are without an obligation for prior negotiation.

It was this mechanism that was used by DHHS Secretary Tommy Thompson in 2001, when he threatened to break the Bayer patents on Ciprofloxacin, in order to import less expensive generic copies for US government stockpiles to treat anthrax poisoning. In the end, Thompson used this threat to reach an agreement with Bayer to cut its prices by 50 percent.

One major challenge in this strategy is to determine the “reasonable and entire compensation” for the use. On the one hand, Gilead can point to the $1,000 per pill price as a basis for the compensation, claiming the patents represent most of the value of the product. The government could counter by demonstrating that Gilead’s prices are excessive, and access is limited to a small portion of persons who need the medicine. Such cases can drag on for years, and given the magnitude of the possible claims that Gilead could make, present very significant risks going forward.

Also, even though the US government can use 28 USC 1948(a) to overcome the rights in the patent, the federal government may face a separate barrier in registering the product with the FDA. Gilead has the exclusive right to rely upon the originators test data to establish the safety

and efficacy of sofobuvir (and its other drugs), in order to obtain FDA marketing approval. (See discussion of FDA Orange Book, below) The Gilead test data rights for sofosbuvir extends through December 6, 2018.

KEI welcomes insight into the issue of the regulatory barriers. There may be a legal way for the FDA to waive the test data exclusivity, or for a product to be distributed without being registered, or not. Alternatively, the US government could submit test data undertaken by parties other than the originator, and for Sofosbuvir, this could include tests underway or completed, including for example two NIH sponsored trials, a trial in France by Inserm-ANRS and a trial in Australia by the Kirby Institute, as well as new trials not yet undertaken. In this regard, trials involving sofosbuvir and ledipasvir fixed dose combinations may be even more important, if this new combination is less expensive to produce and easier to administer than combinations involving biologic drugs such as pegylated interferon and ribavirin.

Four sofosbuvir trials in ClinicalTrials.Gov funded by US government or "other"

1. ClinicalTrials.gov Identifier: NCT01441180
   GS-7977 Alone or With Ribavirin for Hepatitis C
   http://clinicaltrials.gov/ct2/show/NCT01441180
   National Institute of Allergy and Infectious Diseases (NIAID)
   Intervention: GS7977 RBV
   Enrollment: Enrollment: 79

2. ClinicalTrials.gov Identifier: NCT02125500
   Pilot Study to Assess Efficacy and Safety of Sofosbuvir/Ledipasvir (GS-5885)
   Fixed-dose Combination in NS3/4A Protease Inhibitor-experienced Subjects With HCV
   Genotype 1 Infection and HIV Co-infection
   http://clinicaltrials.gov/ct2/show/NCT02125500
   French National Institute for Health and Medical Research-French National Agency fo
   Research on AIDS and Viral Hepatitis (Inserm-ANRS)
   Intervention: Sofosbuvir/Ledipasvir fixed dose
   Estimated Enrollment: 70

3. ClinicalTrials.gov Identifier: NCT02064049
   http://clinicaltrials.gov/ct2/show/NCT02064049
   Surveillance and Treatment of Prisoners With Hepatitis C (SToP-C)
   Kirby Institute
   Intervention: Sofosbuvir and ribavirin
   Estimated Enrollment: 650

4. ClinicalTrials.gov Identifier: NCT01805882
Combination Therapy for Chronic Hepatitis C Infection
http://clinicaltrials.gov/ct2/show/NCT01805882
National Institute of Allergy and Infectious Diseases (NIAID)
Intervention: Drug: Fixed Dose GS-7977/GS-5885, Drug: FDC with GS-9451, Drug: FDC with GS-9669
Estimated Enrollment: 325

If the United States federal government elected to use 28 USC 1498(a) to overcome the patent rights, it would also solve the issue of importing an infringing good. Under 19 USC 1337(l), Unfair practices in import trade, the United States International Trade Commission is required to permit infringing products to enter the United States when use is by or for the United States Government. Note that in:

19 U.S.C. Sec. 1337 - Unfair practices in import trade

(l) Importation by or for United States
Any exclusion from entry or order under subsection (d), (e), (f), (g), or (i) of this section, in cases based on a proceeding involving a patent, copyright, mask work, or design under subsection (a)(1) of this section, shall not apply to any articles imported by and for the use of the United States, or imported for, and to be used for, the United States with the authorization or consent of the Government. Whenever any article would have been excluded from entry or would not have been entered pursuant to the provisions of such subsections but for the operation of this subsection, an owner of the patent, copyright, mask work, or design adversely affected shall be entitled to reasonable and entire compensation in an action before the United States Court of Federal Claims pursuant to the procedures of section 1498 of title 28.

2. State Government Use of HCV patents, without permission from right holder

A separate path would involve a state government acting, under the doctrine of sovereign immunity. In 1999, the US Supreme Court held in a 5 to 4 decision that an instrumentality of the State of Florida could not be sued for patent infringement, in a case involving a patent on a method of financing student loans. The constitutional issues include the tension between the Eleventh and the Fourteenth amendments to the United States Constitution. The Eleventh Amendment bars federal courts from extending suits in law or equity against a state government. The Fourteenth Amendment says that no state may deprive a person of property without due

process or law, and gives the Congress “the power to enforce, by appropriate legislation, the provisions of this article.”

Article XI
The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.

Article XIV
1: All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make o enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

5: The Congress shall have power to enforce, by appropriate legislation, the provisions of thi article.

In *Florida Prepaid Postsecondary Ed. Expense Bd. V. College Savings Bank (98-531) 527 U.S. 627 (1999),* the majority opinion noted “The underlying conduct at issue here is state infringement of patents and the use of sovereign immunity to deny patent owners compensation for the invasion of their patent rights.” [Page 640] The majority opinion said:

> “[A] State’s infringement of a patent, though interfering with a patent owner’s right to exclude others, does not by itself violate the Constitution. Instead, only where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent could a deprivation of property without due process result.” [Page 643]

The Majority noted that patent holders do have remedies for patent infringement by a state, including such possibilities as general tort claims, a general unfair competition suit [Pages 643-4, Footnote 8], and specifically in Florida “Aggrieved parties may pursue a legislative remedy through a claims bill for payment in full, Fla. Stat. § 11.065 (1997), or a judicial remedy through a takings or conversion claim.” [Page 644, Footnote 9].

The Majority complained that Congress was making a case for a uniform system of remedies, but had not established the inadequacy of state remedies, as was required to overcome the Article 11 sovereignty.

The Court overturned the legislative act that had attempted to make States subject to infringement remedies under 35 USC 271(h) and 35 USC 296.

35 U.S. Code § 271 - Infringement of patent

(h) As used in this section, the term “whoever” includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

35 U.S. Code § 296 - Liability of States, instrumentalities of States, and State officials for infringement of patents

a) In General.— Any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity, shall not be immune, under the eleventh amendment of the Constitution of the United States or under any other doctrine of sovereign immunity, from suit in Federal court by any person, including any governmental or nongovernmental entity, for infringement of a patent under section 271, or for any other violation under this title.

(b) Remedies.— In a suit described in subsection (a) for a violation described in that subsection, remedies (including remedies both at law and in equity) are available for the violation to the same extent as such remedies are available for such a violation in a suit against any private entity. Such remedies include damages, interest, costs, and treble damages under section 284, attorney fees under section 285, and the additional remedy for infringement of design patents under section 289.

The majority opinion concluded by finding:

> The historical record and the scope of coverage therefore make it clear that the Patent Remedy Act cannot be sustained under § 5 of the Fourteenth Amendment. The examples of States avoiding liability for patent infringement by pleading sovereign immunity in a federal-court patent action are scarce enough, but any plausible argument that such action on the part of the State deprived patentees of property and left them without a remedy under state law is scarcer still. The statute’s apparent and more basic aims were to provide a uniform remedy for patent infringement and to place States on the same footing as private parties under that regime.[11] These are proper Article I concerns, but that Article does not give Congress the power to enact such legislation after Seminole Tribe.

> The judgment of the Court of Appeals is reversed, and the case is remanded for proceedings consistent with this opinion. [Page 648]

Injunctions for infringement by States

The federal statute on the grant of injunctions for patent infringement is 35 U.S.C. § 283, which consists of a single sentence:

> 35 U.S. Code § 283 - Injunction
>
> The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent on such terms as the court deems reasonable.

The Patent Remedy Act did propose that "remedies (including remedies both at law and in equity) are available for the violation to the same extent as such remedies are available for such a violation in a suit against any private entity." [35 USC 296(b)], but the next sentence in the same paragraph described "such remedies" to "include damages, interest, costs, and treble damages under section 284, attorney fees under section 285, and the additional remedy for infringement of design patents under section 289," an enumeration that omitted section 283 on injunctions.

College Savings had sought a wide range of remedies, including "declaratory and injunctive relief as well as damages, attorney's fees, and costs." [Page 633]

The footnote 11 in the penultimate paragraph of the majority opinion criticizes the dissent for misrepresenting the extent to which the Congressional Act would have exposed states to patent infringement remedies.

> . . . contrary to the dissent's intimation, see post, at 663 (opinion of Stevens, J.), the Patent Remedy Act does not put States in the same position as the United States. Under the Patent Remedy Act, States are subject to all the remedies available to plaintiffs in infringement actions, which include punitive damages and attorney's fees, see 35 U. S. C. §§ 284, 285, as well as injunctive relief, see § 283. In waiving its own immunity from patent infringement actions in 28 U. S. C. § 1498(a) (1994 ed. and Supp. III), however, the United States did not consent to either treble damages or injunctive relief, and allowed reasonable attorney's fees only in a narrow class of specified instances.

The Dissent responded to footnote 11 with footnote 15, which read:

> Footnote 15. The majority's assertion that "the Patent Remedy Act does not put States in the same position as the United States," ante, at 648, n. 11, is misleading. In the case of private infringement suits, treble damages are available only "where the infringer acted in wanton disregard of the patentee's patent rights, that is, where the infringement is willful." Read Corp. v. Portec, Inc., 970 F. 2d 816, 826 (CA Fed. 1992) (reversing the District Court's award of enhanced damages). "On the other hand, a finding of willful infringement does not mandate that damages be enhanced, much less mandate treble damages." Ibid. Attorney's fees are available only in "exceptional" circumstances. 35 U. S. C. § 285. Once it has determined that the case is "exceptional," the district court has discretion whether or not to award attorney's fees and the fees "must be reasonable." Gentry Gallery, Inc. v. Berkline Corp., 134 F. 3d 1473, 1480 (CA Fed. 1998). In addition, attorney's fees are available in limited circumstances in suits against the United States. Ante, at 648, n. 11. The remaining differences between the United States' waiver of sovereign immunity and the Patent Remedy Act are supported by quintessentially federal concerns. This Court has found that "the procurement of equipment by the United States is an area of uniquely federal interest." Boyle v. United Technologies Corp., 487 U. S. 500, 507 (1988). Indeed, the importance of the federal interest in military procurement led this Court to fashion the doctrine of "Government contractors' immunity" without waiting for Congress to consider the question. Id., at 531 (Stevens, J., dissenting). Injunctions are not available against the United States because of the Federal Government's extensive investment in patented military inventions. "[T]he right to enjoin the officer of the United States . . . virtually asserts the existence of a judicial power to close every arsenal of the United States." Crozier v. Krupp A. G., 224 U. S. 290, 302 (1912).

One implication of footnotes 11 and 15 of the decision is that by overturning the Patent Remedy Act, there is no longer a statutory basis for granting injunctions.

Following the Supreme Court opinion in *Florida Prepaid,* there have been efforts to overcome the sovereign immunity defense by seeking injunctions under the *Ex parte* Young doctrine, a strategy that involves obtaining an injunction against individuals working for governments. The extent to which a plaintiff can succeed in overcoming the Article eleven sovereign immunity by bringing a suit against individual state officials is nuanced, technical and narrow, and often litigated in the context of socially controversial issues, such as voting rights, rights of persons with disabilities, health care or environmental protection. The experience in obtaining such injunctions for patent or copyright cases is mixed. In some cases, efforts to obtain such injunctions have been rejected, such as in *Pennington Seed, Inc. v. Produce Exchange* No. 299 457 F.3d 1334 (Fed. Cir. 2006), while in other cases requests have been successful.

The eBay Standard for Injunctions

The risk of an injunction in a non-voluntary use of a patent is not zero, but it is not 100 percent either, both because it is challenging to persuade a court to accept the *Ex parte* Young doctrine, and even when a court considers an injunction, they are not automatic for infringements of intellectual property rights, particularly following the US Supreme Court decision in another case, eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).

In the 2006 eBay v MercExchange decision, Justice Thomas delivered the opinion for a unanimous Court, which set out the four factor test that must be considered in evaluating a request for a permanent injunction.

> According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate:
>
> (1) that it has suffered an irreparable injury;
> (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury;
> (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and
> (4) that the public interest would not be disserved by a permanent injunction.

While in principle the eBay decision did not change the law, it has an enormous practical impact on the way the law is understood by District and Circuit courts. Today, in litigation concerning the remedies for infringement of intellectual property of all kinds, Courts will often be asked to consider a compulsory license to the infringed patent as an alternative to the enforcement of the injunction. This has lead to a significant number of compulsory licenses being issued for infringement of patents in the area of medical devices and diagnostic tests, as well as in cases involving software, mobile computing devices, automobiles, and other technologies. On July 1, 2014, a judge in the Eastern District of Texas used the eBay injunction standard to grant a compulsory license that allowed Globus Medical to sell an “adjustable intervertebral spacer” used for spine injuries, that was based upon the misappropriation of trade secrets, subject to an ongoing royalty of 5 percent for 15 years. (http://www.keionline.org/node/2053).

State compensation for non-voluntary use of a patented invention

One can imagine a number of cases where a state may decide to willfully infringe patent rights without offering compensation, and given the low bar set by the US Supreme Court in Florida Prepaid, which considers aggrieved parties pursuing “a legislative remedy through a claims bill

for payment in full" among the acceptable due process alternatives, there seems to be considerable flexibility. However, in the case of patents on sofosbuvir or other multi-billion dollar drugs, a state decision to break a patent monopoly will likely be more sustainable if the state government has a process for remuneration for the non-voluntary use of the patented invention. It is even more true as regards in the chances of a favorable outcome from an Ex Parte Young injunction case.

The States have considerable flexibility in creating both the standards for the remuneration and the due process for resolving disputes over the amount of the remuneration. For example, a state could adopt a system for remuneration for use of a patent that was paid out of a fund of a fixed size to compensate patent holders, for general patent infringements, or specific uses such as for the treatment of Hepatitis C. A state could provide right to reasonable royalties for infringement, such as the provisions in the Affordable Care Act for biologic patents that are not disclosed on a timely basis. A state could adopt language similar to the the provisions for mandatory licensing of patents necessary to implement a Clean Air Act standard under 42 USC 7608. To reduce uncertainty, a state could create guidelines for the royalty rate, such as the Japanese royalty guidelines. A state could require the compensation to be settled through arbitration, such as the system for compensation for agricultural test data, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which among other things, requires right holders to disclose actual R&D outlays, and information regarding the market share of the infringing product, in order to make a pro-rata allocation of cost sharing, over a time limited period that is shorter than a patent. All of these and other approaches, could be considered, adopted and implemented, as part of a plan to break patent monopolies for drugs for HCV.

FDA Orange Book

In 1979, the federal government created a publication now referred to as the Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, in order to provide information to assist states and and facilitate generic substitution. In 1984, the Hatch-Waxman Act created a new pathway for registering generic pharmaceutical drugs that included a *sui generis* intellectual property right in test data, which consisted of an exclusive right to rely upon data from clinical trials and certain other tests, in an application to the FDA for marketing approval of a pharmaceutical drug. The period of exclusivity was five years for new chemical entity (NCE), or three years for a new indication.

The Hatch-Waxman Act created a process for disclosing certain types of patents on a drug, and creating barriers to registering drugs while those patents are still relevant. Under the FDA rules, as they have evolved over time, the listing of a patent in the FDA Orange Book creates the possibility of a 30 month stay before the FDA can approve an application for a generic drug. The generic applicant can reduce this time, but only if a "district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity)." [21 USC 355 (c)(3)(C)(i)]

For biologic drugs, a different pathway exists outside of the Orange Book system, and includes 12 years of rights in test data, and a complex system of disclosure under nondisclosure rules of relevant patents, and compulsory licenses on non-disclosed patents.

Registration of a Drug with the FDA when a State authorizes infringement of the patent

A state would face the challenges of registering an infringing drug with the US FDA. In addition to the issue of rights in test data, which may or may not be forthcoming from an NIH funded clinical trial, there is the 30 month patent regulatory stay for patents listed in the US FDA Orange Book. A state could wait out the 30 months, or could ask the FDA to consider a non-voluntary license from a state as sufficient to meet the statutory standards for overcoming the Orange Book patents.

3. Private Infringement of HCV patents, without permission from right holder

As noted above, courts can and routinely do permit private parties to make, sell, import and export infringing products, as an alternative to the grant of an injunction to prevent such acts. Such non-voluntary uses of patents are often subject to ongoing royalty payments.

Without waiting for a governor, state legislature or the federal government to lead on the HCV patent issue, a private company, for profit or non-profit, could simply infringe, and litigate a compulsory license under the *eBay* standards for an injunction.

All of the challenges regarding the FDA registration of the product that face a state government will remain, although in a somewhat less emotive context, because the state sovereignty issue is probably considered more provocative than the now common compulsory license under an eBay injunction proceeding.

Unclear in such a scenario would be the reaction of a judge to the assertion by the infringing actor that a decision by a federal judge to forgo the injunction constitutes a sufficient resolution of the patent dispute to allow the registration of the infringing product prior to the expiration of the FDA's 30 month stay for Orange Book patents.

4. Risks Posed by Trade Agreements

Among the risks posed by trade agreements are provisions in trade agreements on damages, injunctions and the linkage of patent status to the registration of drugs.

Damages

On the issue of damages, language from ACTA, and the proposed text in the Trans-Pacific Partnership (TPP) agreement are particularly troublesome. In the TPP, the August 2013 text included the following language, as consensus text:

> In determining the amount of damages . . . its judicial authorities shall have the authority to consider, *inter alia,* any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price.

Without going into details, such as the implication that the standard evokes the Entire Market Value Rule (EMVR), and would ignore actual transaction prices, it is sufficient to acknowledge that the standard, pushed by the Motion Picture Industry Association for copyright infringements, is aggressive and particularly inappropriate for patents.

Given the high "suggested retail price" for Sovaldi and other treatments for HCV, policy makers will want to reflect on this standard, as regards an obligation in a trade agreement that is subject to dispute resolution.

The TPP text does not require super high damages, but it does require TPP members to give judicial authorities the right to grant super high damages. This would be in direct conflict with much of the jurisprudence under 28 USC 1498, and the standards for compensation under 42 U.S. Code § 2187 - Compensation, awards, and royalties. If applied to compulsory licenses, it would conflict with the compensation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the statutory standard for the compulsory licenses in the Affordable Care Act, and it would conflict with some of the proposals suggested above for state remuneration schemes.

Injunctions

The obligation to make injunctions available also creates issues for some of the options available to states, to the extent that a trade agreement is used to sanction a non-compliant state program.

Patentability Standards

In the TPP negotiations, USTR has proposed

> The Parties confirm that: patents shall be available for any new uses or methods of using a known product. . . . a Party may not deny a patent solely on the basis that the product did not result in enhanced efficacy of the known product when the applicant has set forth distinguishing features establishing that the invention is new, involves an inventive step, and is capable of industrial application.

Given the proliferation of patents on sofosbuvir and other HCV drugs, including patents on the uses of products in combination treatments, the TPP provisions on patentability standards make it more difficult for the United States and other governments to curb the granting the type of patents that add little or nothing in terms of R&D incentives, but harm consumers by extending monopolies and discouraging or delaying important follow-on research.

ISDS

Of considerable importance in trade agreements are provisions for investor state dispute settlement (ISDS), which would permit a private party such as Roche, Merck, AbbVie or Gilead to bring private suits to enforce provisions in trade agreements, or more generally to address expropriation of investments. The 2012 U.S. Model Bilateral Investment Treaty (BIT) language published in USTR includes an Article 6: Expropriation and Compensation, which covers both direct and "indirect" expropriation. In the model BIT, USTR allows that:

> Article 6(5). This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with the TRIPS Agreement.

Under an ISDS, the private party and private arbitrators, operating outside of a national court system, would determine the extent to which an action is "consistent with the TRIPS Agreement."

Under ISDS, investors suits against the United States would have to come from investors residing in foreign countries. But today right holders find all sorts of ways to change their legal residency. For example, Pfizer and AbbVie are both currently in the process of attempting relocations of legal residence to avoid US federal taxes. With enough money on the line, holders of key HCV patents would have opportunities and incentives to relocate to bring ISDS actions.

Third party liability

There is considerable pressure from the motion picture and pharmaceutical industries to include provisions in trade agreements to create or expand third liability for infringements, including entities that providing non-patented manufacturing inputs, transport infringing products, or process financial payments for infringe products. All of these measures create potential issues for States or private entities engaging in infringing activities.

5. Patent Buyout

The discussions above address the mechanisms to use patents without permission from patent holders. Governments and insurers might also consider patent buy-out strategies, using either completely voluntary negotiations, or if governments are involved, a non-voluntary taking of the patent. The buyout can be for all uses and all geographic areas of the patented invention, or a field of use (HCV) and a geographic area for a patent. The patent buyout would be justified on the grounds that the patent would be more valuable to society if the products were available at marginal costs, given the fact that the inventions are treating patients with differential health benefits, and the disease is infectious.

In patent buyouts, the critical issue for all concerned will be the price. To the extent that there are multiple products in the same therapeutic class that can be reasonably, even if imperfectly, substituted for each other, there is an opportunity to play one patent holder off against another. If, on the other hand, the only drug combination worth having is sofosbuvir combined with ledipasvir, the negotiation will be challenging, and the price extremely high. Even if the price of the buyout is extraordinarily high, involving tens of billions of dollars, governments would be better off, since they are going to spend tens of billions in any case, but under the buyout they could treat far more people for the same amount of money.

The challenge in a patent buyout scenario is to organize all of the entities that benefit from the buyout to cooperate to finance the buyout. Divided and unorganized, consumers will pay a lot, and get very little. Organized, they can pay less, and get more.

6. Patent Pool

There is in fact a very large and growing number of patents on HCV products, and extensive litigation between many parties. The March 30, 2014 10-Q Report by Gilead uses more than 3,000 words to describe its litigation with Roche, Merck, AbbVie, Idenix and others over sofosbuvir patents, and includes such issues as the AbbVie claim that it has patented the use of the combination of two Gilead drugs, sofosbuvir and ledipasvir, to treat HCV.

Given the importance of combinations and follow on innovation to effectively treat HCV, and the extensive and complex patent claims being filed by various parties, HCV is at risk from patent thickets. In the past, the United States has responded to such cases by mandating that right

holders place patents into a patent pool, or risk seizure of the patents by the federal government. This was previously done for both Aircraft and Radio patents (KEI Research Note 2007:6), and should be considered for HCV.

7. Prize Fund

Senator Bernie Sanders (I-VT) has proposed the elimination of exclusive rights for patents, either for all pharmaceutical drugs or for drugs for HIV/AIDS. This approach, particularly the HIV/AIDS prize fund legislation, S.626 in the 113th Congress, could be modified for HCV. Indeed, one can imagine expanding S. 626 to include treatments for HCV, or other infectious diseases that might appropriate.

8. Customs Issues

As noted above, under 19 USC 1337(l) Unfair practices in import trade, the United States International Trade Commission is required to permit infringing products to enter the United States when use is by or for the United States Government, subject to "reasonable and entire compensation in an action before the United States Court of Federal Claims pursuant to the procedures of section 1498 of title 28."

For imports by entities not protected by 1337(l), there is the possibility, under, 19 USC 1337(d)(1) for the International Trade Commission (ITC) to permit an infringing import, in order to address concerns over:

> "the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers."

Moreover, even if the ITC does allow an infringing import, the President may override the ITC. This was was done, for example, by USTR head Michael Froman, acting on behalf of the President, on August 3, 2013, in a decision to permit imports of infringing Apple Inc. "smart phones and tablet computers that infringe a U.S. patent owned by Samsung Electronics," in the ITC Investigation No. 337-TA-794.

In the absence of a decision by the ITC or the President to permit infringing imports, the products can be manufacturing in the United States. In this regard, note that CIPLA recently built a manufacturing plant in Uganda, to manufacture drugs of similar complexity to the new HCV drugs sold by Gilead and Abbvie, and such an arrangement would likely be possible, if it was legal to make and sell the products in the United States.

9. Concluding Comments

There exist a number of ways that governments can overcome the exclusive rights in patents to expand access to HCV drugs, and address the affordability issues. Each mechanism has its advantages but also risks. Actions by the Federal government or by State governments are feasible, and should be pursued. In the absence of leadership by government officials, private parties can also act.

The federal government has the greatest freedom to act, including to import and register generic versions of drugs. Without changes in federal statutes, the primary barrier to a federal intervention using 28 USC 1498 will be to resolve disputes over the compensation to patent holders --- a process that would likely take several years to play out, and involve huge sums of money. The compensation issue could be managed much better with new laws that created a more predictable framework for setting compensation on HCV drug prices that also addressed concerns over health care budget constraints, such as caps on compensation relating to multiples of actual R&D investments (the approach used in FIFRA), a simple fixed maximum compensation (the approach used in S. 626 for treatments for HIV/AIDS), or as a percentage of outlays on treatment, to mention a few possible approaches.

State governments have a more difficult path forward as regards possible injunctions and to register products with the FDA, but they have one significant advantage -- the ability to create their own norms for compensation and systems of due process for non-voluntary uses of patents, as well as complete immunity from federal suits for damages.

Private parties have available mechanisms that are today fairly a well-known and accepted path forward for a non-voluntary use of a patent, but the outcome will depend upon decisions, first by a district court judge, later by the Court of Appeals for the Federal Circuit, and possibly by the Supreme Court, over injunctions and damages.

A patent buyout effort would have a number of advantages, and in the some scenarios, reduce uncertainty, but require considerable coordination among buyers, and challenges in financing the buyout for an asset that provides benefits over several budget years.

The patent pooling scenario used in 1917 to consolidate aircraft patents or the proposal to replace the HCV patent monopoly with a prize fund are among the more innovative ways forward that require changes our thinking about the role of the patent system in supporting medical innovation. They should at a minimum be modeled and evaluated by policy makers. The National Academies should be asked to consider prize fund alternatives for treatments for hepatitis C, either on its own, or in connection with proposals for a prize fund for HIV/AIDS.