March 10, 2017

Commander
U.S. Army Medical Research and Materiel Command
ATTN: Command Judge Advocate
MCMR-JA, 504 Scott Street
Fort Detrick, MD 21702-5012
Via Fax: +1 (301) 619-5034
Via Email: barry.m.datlof.civ@mail.mil

Dear Command Judge Advocate:

This is the third set of comments signed or cosigned by KEI, including our comments on December 21, 2017 and the joint NGO comments January 12, 2017, with regards to the grant of an exclusive license of patents on a Zika Vaccine by the U.S. Army to Sanofi.[1]

Before responding to the question of the license itself, we offer this comment on the process. We had hoped to obtain answers to several questions about the proposed license, but none have been forthcoming from the Army. Whose interests are served by the lack of transparency: the large French drug and vaccine manufacturer Sanofi, or the U.S. taxpayers and residents who pay for the Army's research budget, and will have to pay if the vaccine is approved by the FDA? The lack of transparency seems to be designed to protect the French company from efforts to avoid compliance with the provisions of 35 U.S.C. § 209 and 35 U.S.C. § 201(f), and to protect the Army from informed criticism of the decision to grant an exclusive license, or their terms.

Our comments today address the issue of the statutory definition of "practical application."

The Army is required to evaluate, before granting an exclusive license on a patent, whether the licensee will bring the invention to "practical application," which is further defined in the Bayh-Dole Act as requiring that the licensee make the invention "available to the public on reasonable terms."[2] As we detail in this submission, courts and other fora in the United States,

[1] Department of the Army, Intent To Grant an Exclusive License of U.S. Government-Owned Patents, 82 Fed. Reg. 8611 (Jan. 27, 2017); Department of the Army, Intent To Grant an Exclusive License of U.S. Government-Owned Patents, 81 Fed. Reg. 89087 (Dec. 9, 2016).
[2] 35 U.S.C. § 201(f).

the United Kingdom, South Africa, and the World Trade Organization all have taken the position that “reasonable terms” includes, logically, considerations of price.

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Practical Application

The term “practical application” is mentioned seven times in 35 U.S.C. § 209 as a condition for the grant of an exclusive license on a federally-owned patent, including:

- once in § 209(a)(1)(A),
- twice in § 209(a)(2),
- once in § 209(a)(3),
- once in § 209(c) and,
- twice in § 209(d)(3)(A).

Practical application is defined in 35 U.S.C. 201(f) as follows:

> (f) The term “practical application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and *that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms*. (Emphasis added.)

“Available to the public on reasonable terms” is thus a statutory requirement.

The definition is <u>not</u> simply “available to the public.” The definition is “available to the public on reasonable terms.” When an agency only requires a product to be available on <u>any</u> terms,

including at unreasonable prices, the public is denied the protection that the statute seeks to offer.

Statements by Former Senators Bayh and Dole Regarding Reasonable Terms

Some patent holders have argued that "available to the public on reasonable terms" does not have anything to do with the price — as if there is some other set of terms that excludes price that are covered by the statute. In support of this view, rights holders have referred to statements by former Senators Birch Bayh and Bob Dole, including an April 2002 letter to the Editor of the Washington Post,[3] signed by both, and a statement by Senator Bayh at an NIH meeting on the 2004 request for the use of march-in rights on the patents on the HIV drug ritonavir.[4]

The notion that "available to the public on reasonable terms" does not extend to the price is itself an unreasonable interpretation of the plain language of the statute, which is anchored by the context of "available to the public." Why would Senators Dole and Bayh make that argument? Like many former members of Congress, both Dole and Bayh took lucrative jobs in Washington, DC, to influence the Congress and the Executive branch. Both have several commercial conflicts. In Senator Bayh's case, he has even argued more than one side of the issue, depending upon who, at the time, was paying him.

Bob Dole joined the law and lobbying firm Verner, Liipfert in 1997. In 1998, Pfizer hired Dole to promote the use of Viagra.[5] In 2000, Bob Dole also filed lobbyist reports for Bob Dole Enterprises. From 2000 to 2002, Bob Dole Enterprises listed the pharmaceutical company Johnson and Johnson as its largest client, paying $820,000 in fees in three years.

Senator Bayh also became a lobbyist and a paid influencer after leaving the senate in 1981.

In 1997, Bayh was hired by Cellpro, Inc. — a small Washington State firm manufacturing an FDA medical device that was used in bone marrow transplants — to pursue a march-in case against Johns Hopkins University over NIH-funded patents. In a March 3, 1997 petition, Birch Bayh and Lloyd N. Cutler (who had served as White House Counsel for Jimmy Carter and Bill Clinton) asked Health and Human Services Secretary Donna E. Shalala to grant a march-in license to CellPro. The petition focused on the obligation to set "reasonable terms" in the licensing of the invention, and the impact of the licensing decisions on the prices faced by consumers. Bayh and Cutler wrote that "the interests of the public which paid for the research that led to the patents and is now being asked to pay again — cry out for a far lower royalty payment by CellPro." The petition also made reference to royalty layering as "a common problem that leads to

[3] Birch Bayh and Robert Dole, "Our Law Helps Patients Get New Drugs Sooner," *Washington Post*, A28 (Apr. 11, 2002).
[4] Statement of Senator Birch Bayh to the National Institutes of Health, May 25, 2004, available at: http://www.essentialinventions.org/drug/nih05252004/birchbayh.pdf
[5] "Pfizer Hires Bob Dole for TV Ad Campaign," Associated Press, December 12, 1998, available at: http://articles.latimes.com/1998/dec/12/business/fi-53139

unreasonably high royalties (and prices of medical care) that should be dealt with by regulation."[6] They wrote:

> "CellPro submits that there may well be reason for the government to adopt regulations covering situations like the present where the same product may be claimed to be covered by patents arising out of work done by more than one federal grantee. Moreover, investigation may be needed to determine whether the royalty "layering" that plainly exists in the present case -- where federal grantee Johns Hopkins has licensed to Becton Dickinson, which apparently marked up the price and relicensed to Baxter, which in turn clearly marked up the price and relicensed to Systemix and Applied Immune Systems -- is a common problem that leads to unreasonably high royalties (and prices of medical care) that should be dealt with by regulation."

On June 14, 2001, Birch Bayh joined Venable, Baetjer, Howard & Civiletti as a partner, where he focused on "the firm's growing public policy advocacy practice." The following year, Bayh joined Dole in writing a letter to the editor of the Washington Post attacking the notion expressed by Professors Peter Arno and Michael Davis — argued in a March 27, 2002 Washington Post editorial[7] — that "available to the public on reasonable terms" includes a requirement to set "reasonable prices."

Bayh also took this position in the 2004 ritonavir march-in case, when he claimed that he was not paid to provide evidence in the hearing. But, Bayh did not disclose that Venable, the firm where he was a partner, represented Abbott, the holder of the ritonavir patents. Bayh would continue to appear on behalf of the firm to give evidence of what the Bayh-Dole Act meant, including, for example, in a December 23, 2010 amicus brief in *Stanford University v. Roche Molecular Systems*,[8] where the Supreme Court rejected Bayh's interpretation.[9]

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[6] Lloyd N. Cutler and Birch Bayh, Letter to Secretary of Health and Human Services Donna E. Shalala, March 3, 1997, available at: https://ia800409.us.archive.org/19/items/nih_cellpro/foia_cellpro1.pdf.

[7] Peter Arno and Michael Davis, "Paying Twice for the Same Drugs," *Washington Post*, A21, Mar. 27, 2002, https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/; Peter Arno and Michael Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 Tulane L. Rev. 631-98 (2000).

[8] Brief of Birch Bayh as *Amicus Curiae* in Support of Petitioner (Dec. 23, 2010), *Stanford Univ. v. Roche Molecular Systems, Inc.*, 563 U.S. 776 (2011), available at: https://ogc.stanford.edu/sites/default/files/brief_amicus_curiae_of_birch_bayh_december_23_2010.pdf; John F. Cooney and Michael A. Gollin, *Venable team files Amicus Brief for Senator Bayh in support of Bayh-Dole Act in Stanford v. Roche*, January 14, 2011, available at: https://www.venable.com/venable-team-files-amicus-brief-for-senator-bayh-in-support-of-bayh-dole-act-in-istanford-v-rochei-01-14-2011/.

[9] *Stanford Univ. v. Roche Molecular Systems, Inc.*, 563 U.S. 776 (2011); James E. Nelson and Stephanie T. Anelli, *Stanford v. Roche: The Importance of Precise Contract Drafting*, Venable (July 2011), https://www.venable.com/files/Publication/cef85449-cb09-463a-ab1e-26f57aa40ffc/Preview/PublicationAttachment/257797c5-1f44-46c8-a8be-375f530357eb/Stanford_Roche_7-19-11.pdf

Bayh argued in 2004 that Arno and Davis misinterpreted the legislative history of the Bayh-Dole Act as regards protections against unreasonable prices.[10] However, Bayh's criticism focused on the nuances of the legislative history of the march-in provisions of the Bayh-Dole Act (35 U.S.C. § 203), and not the arguments made by Arno and Davis with regards to the way that the courts have interpreted "reasonable terms" to include a "reasonable price." And, while Bayh's written submission for the ritonavir case is correct to point out that the section of the Committee report (S. Rep. No. 96-480) on S. 414 (which became the Bayh-Dole Act) that addresses "windfall profits" does not apply to the current march-in rights provision, he does not address the definition of "practical application." Bayh also acknowledged that there were concerns about patent owners taking unfair advantage of the government-funded patent rights, a topic for which the march-in provision was often cited as a remedy in the discussion of more than one bill on government-funded patent rights.

In further evaluating the legislative history of the march-in provision, Bayh stated that Arno and Davis misquoted an exchange at a 1979 Committee hearing on S. 414 between himself and the Comptroller General of the United States, Elmer Staats, to imply that Bayh believed that the intention of the march-in provision of the bill was to prevent "the large, wealthy corporation to take advantage of Government research dollars and thus to profit at the taxpayers' expense." Bayh is correct to note that this statement was not made with explicit reference to the march-in provision, however, as Bayh himself noted in his own 2004 testimony on the ritonavir case, he stated in his 1979 testimony that he believed that, overall, "We thought we had drafted this bill in such a way that this was not possible." Moreover, neither his statement nor Staats' addressed the definition of "reasonable terms" or the prices of patented inventions.[11] Thus, it appears that, in 1979, Bayh did believe that the bill was drafted to prevent "corporations [taking] advantage of Government research dollars" and from unduly "profit[ing] at the taxpayer's expense," a position he also took in the 1997 Cellpro case (see above), where he expressed concern over the impact of the patent licensing terms on the prices charged to consumers.

Bayh also argued that the NIH has concluded that reasonable pricing requirements in relation to industry collaborations is contrary to the Bayh-Dole Act. The NIH language he quotes — from a non-binding report issued 21 years after the passage of the Bayh-Dole Act — does not, however, make any legal conclusions, but rather argues that the Bayh-Dole Act should be interpreted in light of present-day policy realities.

Reasonable Terms in U.S. Case Law

"Reasonable terms" has been regularly interpreted in case law in both federal and state courts to include price.

[10] Statement of Senator Birch Bayh to the National Institutes of Health, May 25, 2004. Available at: http://www.essentialinventions.org/drug/nih05252004/birchbayh.pdf

[11] *The University and Small Business Patent Procedures Act*, Hearings before the S. Comm. on the Judiciary on S. 414, 96 Cong. 44 (May 16, 1979).

In *American Liberty Oil Co. v. Fed. Power Comm'n*, the Fifth Circuit Court of Appeals interpreted the Natural Gas Act's provision allowing the Federal Power Commission to establish "reasonable terms and conditions" as including price.[12] *See also*, *United States v. Mississippi Vocational Rehab. for the Blind*, 812 F. Supp. 85, 87-89 (S.D. Miss. 1992) (interpreting 20 U.S.C. § 107d-3 provision allowing for federal entities to negotiate reasonable terms as including price).

In a case regarding the abuse of monopoly power, the Sixth Circuit Court of Appeals in *Byars v. Bluff City News Co.* stated that "The difficulty of setting reasonable terms, especially price, should be a substantial factor when confronted with the latter situation."[13]

In *Topps Chewing Gum, Inc. v. Major League Baseball Players Ass'n*, 641 F. Supp. 1179 (S.D.N.Y. 1986), an antitrust case, the Court recounted facts on the record, including a willingness of the players association to negotiate a license on "commercially reasonable terms," which the Court "assume[d] means at a price higher than Topps currently pays under its player contracts." *Id.* at 1191.

In contractual and commercial matters governed by the Uniform Commercial Code, Art. 9, § 610, on the disposition of collateral after default, contains an official comment on the "Relevance of Price" that suggests that price may not allow for a per se violation, but is to be considered: "While not itself sufficient to establish a violation of this Part, a low price suggests that a court should scrutinize carefully all aspects of a disposition to ensure that each aspect was commercially reasonable." See also *68A Am. Jur. 2d Secured Transactions* § 646 (1993) (stating that price is a term of commercial reasonableness, but low price alone will not render a sale commercially unreasonable).

Under the proceeds test under Article 9, some courts have accordingly held that price is a term of commercial reasonableness. *See, e.g.*, *ITT Indus. Credit Co. v. Chasse*, 25 U.C.C. Rep. Serv. (CBC) 914, 917-18 (Conn. Super. Ct. 1978); *Farmers Bank v. Hubbard*, 276 S.E.2d 622, 626-27 (Ga. 1981) (price is term of commercial reasonableness that secured party must establish is fair and reasonable); *McMillian v. Bank S., N.A.*, 373 S.E.2d 61, 62 (Ga. Ct. App. 1988) (sale's method and manner were commercially reasonable, but that price was a "term"); *FDIC v. Herald Square Fabrics Corp.*, 439 N.Y.S.2d 944, 955 n.8 (N.Y. App. Div. 1981) (stating that a "wide or marked discrepancy in disposal and sale prices is an independently adequate reason to question the commercial reasonableness of a disposition").

Reasonable Terms in U.K. Patent Law

In the United Kingdom, the Patents Act 1977 includes a "reasonable terms" requirement in § 48A, on compulsory licensing in the case of WTO proprietors, providing for the ability to obtain

[12] 301 F.2d 15 (5th Cir. 1962).
[13] 609 F.2d 843, n.58 (6th Cir. 1979).

compulsory licenses in cases where "demand in the United Kingdom for that [patented] product is not being met on reasonable terms," or for a refusal to license on reasonable terms.[14] The U.K. Manual of Patent Practice, an official government document provided by the Intellectual Property Office, explains that the requirement of reasonable terms is meant to contemplate price:

> **48A.03**
> The applicant needs to show that such a demand is not being met on reasonable terms. What constitutes "reasonable terms" depends on a careful consideration of all the surrounding circumstances in each case, eg the nature of the invention, the terms of any licences under the patent, the expenditure and liabilities of the patentee in respect of the patent, and the requirements of the purchasing public. The price charged by the patentee should be a bona fide one and not one adopted to suppress or depress demand.[15]

The Manual of Patent Practice cites the case of *Brownie Wireless Co Ltd's Applications* (1929) 46 RPC 457 as instructive. In that case, the Court addressed the question of reasonable terms in a case involving a refusal to license patents used for radio amplifiers. The case involved a prior version of the UK patent law (§ 27 of the Patents and Designs Act 1907 and 1919), which provided for compulsory licenses in cases of an abuse of the patent right, explicitly including excessive pricing.[16] The Court stated that "reasonable terms" was an "elastic phrase:"

> The grant of the licence which is refused must be a grant "on reasonable terms", an elastic phrase which can only be construed with certainty with reference to the actual facts of each particular case. No one can hope to lay down any exhaustive rules to enable the question whether the terms of a proposed licence are reasonable or not to be answered with certainty in every case. The answer to the question must in each case depend on the careful consideration of all the surrounding circumstances. The nature of the invention covered by the patent, the terms of the licences (if any) already granted, the expenditure and liabilities of the patentee in respect of the patent, the requirements of the purchasing public, and so on.[17]

In the case of *Cathro's Application* (1934) 51 RPC 75, the Court addressed an application for a compulsory license of patents pertaining to electric valves, on grounds that demand was not being met on reasonable terms under § 27 of the Patents and Designs Acts 1907 to 1932.[18] The Court cited *Brownie Wireless*, stating:

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[14] The Patents Act, 1977 (as amended), Section 48A(1)(a)-(b).
[15] The Manual of Patent Practice is available at https://www.gov.uk/guidance/manual-of-patent-practice-mopp.
[16] *Brownie Wireless Co Ltd's Applications* (1929) 46 RPC 457. Available at https://goo.gl/oK9KBY.
[17] *Id.* at 473.
[18] *Cathro's Application* (1934) 51 RPC 75. Available at https://goo.gl/FUbKe2.

> Now I think in the first place that the expression "on reasonable terms" in paragraph (c) refers mainly to the price charged for the patented article, and I am fortified in this view by a consideration of the summary of the kinds of abuses dealt with by Section 27 given by Mr. Justice Luxmoore in Brownie Wireless Company's Applications (46 RP.C. at page 471) where the reference to "excessive price" (see line 31) clearly refers to the abuse covered by paragraph (c). No doubt, however, this statement of the 30 learned Judge should not be considered to be exhaustive as to the scope of the paragraph, and it may be that in some cases other terms than those referring merely to price should be taken into account.[19]

Reasonable Terms in South African Patent Law

South Africa has a similar provision in its patent law for compulsory licenses where there has been an abuse of the patent right, including where "demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms."[20]

In a case on this issue, *Afitra Ltd v. Carlton Paper of SA* 1992 BP 331, the Court of the Commissioner of Patents referred to the UK decisions in *Cathro's Application* and *Brownie Wireless* among others as being persuasive, and held that "on the charge of not granting a licence, the Court should be provided with evidence indicating, with reasonable precision, what reasonable terms are."[21] While the compulsory license in that case was denied, it failed because the petitioner had not met its evidentiary burden of demonstrating the price to be unreasonable.

Reasonable Terms as Interpreted by the World Trade Organization

In the dispute settlement case of Mexico-Telecoms brought before the World Trade Organization (case DS204), the WTO addressed the question of what constituted "reasonable terms." The complaint brought by the United States alleged, *inter alia*, that Mexico had violated its commitments under GATS by failing to ensure access to and use of public telecommunications transport networks and services on reasonable and non-discriminatory terms and conditions for the supply of basic and value-added telecommunications services.[22]

The United States put forward an argument regarding restricted supply directly linked to pricing:

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[19] *Id.* at
[20] Patents Act No. 57 of 1978, section 56(2)(c). Available at http://www.cipc.co.za/files/9513/9452/7965/Patent_Act.pdf.
[21] *Afitra Ltd v. Carlton Paper of SA* 1992 BP 331, available at http://www.wipo.int/scp/en/exceptions/replies/safrica.html.
[22] Available at https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds204_e.htm.

> IV.230 In terms of the context, the United States argues that the interconnection obligations of Section 2 are especially important for the cross-border supply of basic telecom services – particularly in markets like Mexico, which legally bar foreign service suppliers from owning facilities and therefore force foreign suppliers to rely on the major supplier to deliver their services to the end-user. In such cases, foreign suppliers have no choice but to pay a domestic service supplier (such as Telmex) an interconnection rate to terminate their calls. As a result, the major supplier has the power and incentive to price this input at levels which extract as much revenue as possible from cross-border suppliers. Thus, by raising the wholesale price of cross-border interconnection, the major supplier has the power to raise the retail price, reduce demand for the retail service, and thereby restrict the cross-border supply of services into Mexico.

The Panel found that “terms” would implicitly include pricing elements:

> VII.325 As discussed in part B of these findings, the words "terms and conditions" may have many meanings. In relation to contracts and agreements, the word "terms" is defined to mean "conditions, obligations, rights, price, etc., as specified in contract or instrument", while "condition" is defined, inter alia, as "a provision in a will, contract, etc., on which the force or effect of the document depends". **Although the words "terms" and "conditions" are closely related, and are frequently used concurrently, the ordinary meaning of the word "terms" suggests that it would include pricing elements, including rates charged for access to and use of public telecommunications transport networks and services.** (Emphasis added.)

Conclusion

In our past submissions, provided as separate attachments along with this letter, we have argued that an exclusive license in this case is contrary to provisions in the Bayh-Dole Act that require that the Army evaluate the “reasonable and necessary” incentives required by Sanofi. Sanofi already receives significant funding from the government to conduct clinical trials, has a CRADA with the Army, and would receive both significant data exclusivity protections and a priority review voucher for successfully bringing a Zika vaccine to market.

If, however, the Army decides to grant an exclusive license, it has a clear obligation to ensure that the license includes terms that provide for a reasonable price.

We request a meeting to discuss these issues with you in further detail.

Sincerely,

Andrew S. Goldman, Esq.
Counsel, Policy and Legal Affairs
andrew.goldman@keionline.org

Zack Struver
Communications & Research Associate
zack.struver@keionline.org

James Love
Director
james.love@keionline.org

Knowledge Ecology International
1621 Connecticut Ave NW Suite 500
Washington, DC 20009
+1 (202) 332-2670
http://keionline.org