

**IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF
THE NORTH AMERICAN FREE TRADE AGREEMENT
AND THE UNCITRAL ARBITRATION RULES (1976)**

BETWEEN:

ELI LILLY AND COMPANY

Claimant/Investor

AND:

GOVERNMENT OF CANADA

Respondent/Party

(Case No. UNCT/14/2)

SECOND EXPERT REPORT OF T. DAVID REED

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I. OVERVIEW

1. I am filing this second report in order to respond to the second report that Mr. Erstling has filed on behalf of Eli Lilly (Claimant) in this arbitration. Mr. Erstling and I agree on the single most important point: there is nothing in the Patent Cooperation Treaty (PCT) preventing Canada, or any other Contracting State, from establishing whatever laws it chooses relating to the substantive conditions for patentability of an invention.¹ The determination of whether a patent should be granted lies exclusively with each national (or regional) office as per the requirements of each individual national law.

2. However, in his response to my first expert report, Mr. Erstling claims that I have misconstrued the provisions of the PCT and supporting documents. Mr. Erstling asserts that the PCT and the *Regulations under the Patent Cooperation Treaty* (Regulations) describe everything that PCT Contracting States may require to be included in a PCT patent application. In particular, he concludes that PCT Contracting States are limited to requiring only an explicit indication of the claimed utility in the patent application.² He reaches this conclusion because of the rule in the PCT that individual PCT Contracting States cannot have requirements relating to “form and contents” beyond what is provided in the PCT and Regulations.³ Based on his understanding of the PCT, Mr. Erstling asserts that the Government of Canada is in violation of Article 27(1) and Rule 5 in requiring that the basis of a sound prediction of utility be included in the patent application at the time of filing.

3. I continue to disagree with Mr. Erstling. In my opinion, Mr. Erstling overstates the meaning of “form and contents” in the PCT. In this report, I will address Mr. Erstling's assertions and present the basis for my disagreement with his characterizations of the PCT and its requirements. To be clear, while I will only respond to those parts of

¹ Erstling Second Report, at para. 1.

² Erstling Second Report, at para. 7.

³ Erstling Second Report, at para. 3.

Mr. Erstling's second report that I believe require a response, I have not changed any of my opinions from my first report. I continue to rely on and endorse all of my original opinions.

II. THE PCT DOES NOT RESTRICT CANADA'S DISCRETION TO IMPLEMENT SUBSTANTIVE PATENTABILITY REQUIREMENTS

A. The text of Article 27 allows Canada to implement its substantive patentability requirements

4. Mr. Erstling alleges that Canada is in violation of its obligations under Article 27 of the PCT as a result of Canada's substantive requirement that an applicant disclose the basis of its sound prediction of utility in its patent application. According to Mr. Erstling, Canada is in violation of the "form and contents" requirement in Article 27(1) by requiring more than an explicit indication of utility at the time of filing. I disagree. In all my years of practice in filing PCT applications and teaching other applicants how to do the same, I have never interpreted Article 27(1) in the restrictive way suggested by Mr. Erstling. In my view, Mr. Erstling's conclusion is inconsistent with the text of Article 27 as a whole.

5. Article 27(1) states:

No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations.⁴

6. Under Mr. Erstling's interpretation of Article 27(1), states are limited to requiring only an explicit indication of the utility of the claimed invention in the International Application (IA) at the time of filing.⁵ He uses Rule 5.1 of the Regulations to support this assertion. I disagree. Any such explicit indication is merely a formal requirement and does not limit the discretion of states to prescribe substantive

⁴ *Patent Cooperation Treaty*, World Intellectual Property Organization (1970), Article 27(1) ("*Patent Cooperation Treaty*") (**R-037**).

⁵ Erstling Second Report, at para. 17.

patentability requirements. In drawing the conclusion he does, Mr. Erstling overlooks the remaining text of Article 27 itself.

7. Article 27(5) provides important context for 27(1). It states:

Nothing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires. In particular, any provision in this Treaty and the Regulations concerning the definition of prior art is exclusively for the purposes of the international procedure and, consequently, any Contracting State is free to apply, when determining the patentability of an invention claimed in an international application, the criteria of its national law in respect of prior art and other conditions of patentability not constituting requirements as to the form and contents of applications.⁶

8. In my practice, I have always viewed this language as crucial to understanding what “form and contents” means in Article 27(1). Article 27(5) makes clear that the freedom of states to prescribe substantive conditions of patentability is absolute – it is not affected in any way by other provisions of the PCT (such as Article 27(1)) or the Regulations (such as Rule 5). In both my practice and my teaching, I have always understood that this means a PCT Contracting State can have a substantive condition of patentability which must be disclosed in an IA.

9. As support for my understanding, in my first report I mentioned the example of Japan. Japan is a country which, like Canada, requires that certain disclosures related to its substantive conditions of patentability be provided in the patent application itself. In his second report, Mr. Erstling took issue with my Japan example.⁷ He asserted that I was mixing sufficiency of disclosure with the filing requirements of an IA.⁸ Mr. Erstling pointed to Article 27(6) to argue that sufficiency of disclosure was a matter of national law that was not relevant to the form and contents requirements of the IA. I disagree. Article 27(6) provides:

⁶ *Patent Cooperation Treaty*, Article 27(5) (**R-037**) (emphasis added).

⁷ See Reed First Report, at para. 43.

⁸ Erstling Second Report, at para. 9.

The national law may require that the applicant furnish evidence in respect of any substantive condition of patentability prescribed by such law.

10. I do not see how it matters whether a requirement to include additional information in an IA is labeled a disclosure requirement or a requirement of some other condition of patentability. Regardless of the label applied, the fact is that the information must still be in the IA at the time of filing. As I discussed in my first report, under many national laws and under the PCT itself, new matter cannot be added to the IA after filing.

11. In essence, Mr. Erstling appears to be claiming Article 27's grant of complete freedom to Contracting States with respect to substantive conditions of patentability does not give a national law the freedom to require that an applicant make disclosure in the patent application itself. In all my years of practice under the PCT, I have never read Article 27(6) to suggest, as Mr. Erstling seems to, that a PCT Contracting State cannot require certain information to be disclosed in a PCT application itself.

12. In my opinion, a reading of the full text of Article 27 in its entirety contradicts Mr. Erstling's assertions. The "form and contents" requirements of the PCT are strictly a procedural template, and Contracting States are expressly allowed to prescribe substantive conditions of patentability and to require applicants to furnish evidence that those substantive conditions have been satisfied at the time of filing. The PCT as a whole is clear that it is a procedural treaty, and applicants must respect the national laws in the jurisdictions in which they are applying for patent protection.

B. The Washington Conference Notes confirm my understanding of the PCT

13. My understanding of the PCT is supported by the official materials prepared and published by WIPO on the PCT negotiations. When the PCT was signed in 1970, WIPO concurrently issued extensive written materials explaining the meaning of the treaty and how it should be interpreted and applied. Those papers, the *Records of the Washington Diplomatic Conference on the PCT 1970*⁹ (Washington Conference), serve as an

⁹ Records of the Washington Diplomatic Conference on the Patent Cooperation Treaty (1970) Final Text of the Treaty and Notes ("*Washington Diplomatic Conference*") (C-112).

annotated PCT text, explaining what the Contracting States intended by each article. The Washington Conference papers provide important context in interpreting the PCT.

14. The Notes to Article 27 state:

PARAGRAPH (1): The requirements relating to form and contents are principally provided for in Articles 3 (The International Application), 4 (The Request), 5 (The Description), 6 (The Claims), 7 (The Drawings), and 8 (Claiming Priority), and the Rules pertaining to these Articles (mainly Rules 3 to 13). The words “form or contents” are used merely to emphasize something that could go without saying, namely, that requirements of substantive patent law (criteria of patentability, etc.) are not meant.¹⁰

15. The Notes to Article 27 are clear that the phrase “form and contents” is to be understood in its generic sense. Substantive patent law, including criteria of patentability, are not included under “form and contents” and are therefore free from any restrictions under Article 27(1).

C. Mr. Erstling’s suggestion that Rule 5 of the Regulations restricts Canada’s discretion to implement its substantive patentability criteria is incorrect

16. The Regulations (or Rules) were issued by WIPO to provide additional context in interpreting the treaty provisions. Mr. Erstling and I agree that Rule 5 is relevant to interpreting Article 27. The Note to Article 27 refers to Article 5 for matters related to the description (including utility).¹¹ Article 5 states:

The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.¹²

17. Article 5 gives no express guidance relevant to utility, nor to the list of requirements of a description under the PCT. However, additional guidance for interpreting Article 5 is provided by Rule 5.1 of the Regulations.¹³

¹⁰ *Washington Diplomatic Conference*, P. 35, Notes to Article 27 (emphasis added) (C-112).

¹¹ *Washington Diplomatic Conference*, P. 35 (C-112).

¹² *Patent Cooperation Treaty*, Article 5 (R-037).

¹³ *Washington Diplomatic Conference*, Rule 5 (C-112).

18. Rule 5.1 lists the information that the description shall include.¹⁴ Regarding the manner of the description relating to utility, Rule 5.1(a)(vi) states that the description shall:

[...] indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry and the way in which it can be made and used, or, if it can only be used, the way in which it can be used; the term "industry" is to be understood in its broadest sense as in the Paris Convention for the Protection of Industrial Property.¹⁵

19. Unless a different order of information would better describe the invention, the order of presentation listed in Rule 5.1(a) should be followed in all IAs (Rule 5.1(b)) and the sections labeled as indicated (Rule 5.1(c)). This is quite obviously a form requirement, relating to the procedural formalities of how applicants must present the information contained in their application.

20. Mr. Erstling interprets Rule 5 as imposing a strict limitation on domestic legal systems. Essentially, he argues that all that a PCT Contracting Party can require in the description is an ‘explicit indication’ of utility. However, Mr. Erstling reads this limit into Rule 5, and his view is not supported by the text of the Regulations or the PCT. All that is required by Rule 5 is that an applicant must give an indication of the way the invention can be used if it is not obvious. Further, the Notes to Article 27(1) clearly state that “form and contents” do not relate to substantive conditions of patentability. Mr. Erstling’s rationale finds no support in either the treaty text or the Regulations.

21. Rule 5 supports my conclusion above that the phrase “form and contents” relates to the generic categories of information that must be included in the description, and not to specific requirements of what must or may not be included in the material disclosed in

¹⁴ For example, Rule 5 lists the title, the applicable technical field, the background art including the advantageous effects of the claimed invention over the prior art, the disclosure of the invention (as mentioned in Article 5), a brief description of any drawings, the best mode and, if needed an explicit indication of utility of the claimed invention.

¹⁵ *Washington Diplomatic Conference*, pp. 83-84 (C-112).

each of the broader categories. Mr. Erstling is reading requirements into the text of the PCT and the Regulations that simply do not exist.

III. THE PURPOSE OF THE PCT IS CONSISTENT WITH ALLOWING STATES FLEXIBILITY ON HOW THEY IMPLEMENT THEIR OWN SUBSTANTIVE PATENTABILITY REQUIREMENTS

22. Throughout his first and second reports, Mr. Erstling alleges that Article 27 is fundamental to the purpose of the PCT. He argues that Canada’s requiring disclosure of the basis for a sound prediction of utility at the time of filing, thwarts the purpose of the PCT.

23. As I have shown above, Canada is compliant with Article 27. In any case, I continue to disagree with Mr. Erstling that the way he is interpreting Article 27 is a core purpose of the PCT. Nowhere does the official statement of the aims of the PCT mention the “fundamental,” “central” or “basic” function of the Treaty repeatedly mentioned by Mr. Erstling.

24. The Washington Conference papers explain the fundamental purposes of the PCT. Principal among these objectives are (i) procedures to obtain legal protection for inventions;¹⁶ and (ii) the dissemination of technical information and the organization of technical assistance, particularly for developing countries.¹⁷ These objectives confirm my understanding that the PCT was intended to simply provide a procedural template for patent applicants and to leave the substantive conditions of patentability and their implementation to PCT Contracting States.

25. Going further into the Post-Conference documents,¹⁸ it is apparent that the drafters intended that the PCT benefit both Contracting States (in the form of the international search report and possibly an international preliminary examination report)

¹⁶ *Washington Diplomatic Conference*, pp. 746 -747 (C-112).

¹⁷ *Washington Diplomatic Conference*, pp. 746 -747 (C-112).

¹⁸ *Washington Diplomatic Conference*, p. 754, paras. 84 et seq. (C-112).

as well as patent applicants. For example, applicants have the benefit of at most a single redrafting of applications for the purposes of “form and expression” and translation when utilizing the PCT as opposed to many under a non-PCT practice.¹⁹

26. An example of the purpose of the PCT is again exemplified by Japan. Before Japan signed on to the PCT, Japanese practice required that the claims be at the beginning of the application, followed by the description and any drawings. Under the PCT (and in most national practices) the claims are placed after the description, at the end of the application. When adopting the PCT, Japan accepted the formal order of presentation specified in the PCT and could not require applicants to reformat applications to comply with pre-PCT requirements. Not having to reformat applications to meet a variety of local formal requirements was both time and cost-effective for applicants. The Japan example shows exactly the value of the PCT to both applicants and Contracting States.

27. It is important for applicants to know that upon entering the national phase in a variety of countries, they will not have to make amendments to comply with the myriad formal requirements in each jurisdiction. Article 27(1) provides that these formalities (the form and contents) under the PCT will be accepted by each Contracting State. In my opinion, the PCT has significant value and is the filing method of choice for applicants seeking international patent protection even though applicants still have to ensure that their IA meets the specific substantive content requirements of each national law where they want protection.

¹⁹ *Washington Diplomatic Conference*, pp. 754-755, para. 92 (C-112) (“If the applicant is not following the international procedure offered by the Treaty, he must start preparations for filing abroad three to nine months before the expiration of the priority period. He must prepare translations of his application and must have them put in a more or less different form for each country. Under the Treaty, the applicant, within the priority year, makes only one application (the international application), which may be identical both as to language and form with his own national application, or which involves one – and only one – translation and redrafting. True, the cost of further translations has to be met eventually, but not until eight or more months later than under a procedure which does not use the Treaty, and only if, having seen the international search report, the applicant is still interested in the countries concerned. Moreover, the – even greater – cost of redrafting (recasting as to form and expression) for each and every country does not arise, even later, or arises only to a limited extent (when the claims or the description are amended).”) Also see Reed Report, at para. 15.

IV. THE PRACTICE OF WIPO AND PCT CONTRACTING STATES ESTABLISHES THAT THE PCT DOES NOT RESTRICT HOW STATES CAN IMPLEMENT THEIR SUBSTANTIVE PATENTABILITY REQUIREMENTS

28. The flexibility afforded to member states by the PCT in terms of how they can implement their substantive patentability requirements is demonstrated by (i) the PCT's own examination Guidelines; (ii) the WIPO training materials; and (iii) the practice of various PCT Contracting States. Each will be discussed in the following sections.

A. The Examination Guidelines allow for flexibility

29. Mr. Erstling's assertion that all that is required at the time of the patent application is an explicit indication of the claimed utility is not supported by the materials relied upon by examiners in the International Preliminary Examining Authority (IPEA), namely the International Search and Examination Guidelines (Examination Guidelines).

30. Ultimately, the determination of whether or not an invention has utility will be made by a person of ordinary skill in the art (POSITA). During PCT Chapter II examination, an IPEA examiner will assume the position of a POSITA. The IPEA examiner will look at the claimed invention in light of the disclosure and prior art in the International Search Report, and will render a non-binding opinion on the three criteria for patentability – novelty, inventive step and utility.²⁰

31. The Guidelines relied upon by the IPEA examiners provide further direction: first, the examiner must determine what the applicant has claimed; and second, whether the claimed invention has utility.²¹ The Guidelines note that in most cases, industrial

²⁰ At times relevant to the application that is the subject of this arbitration (pre-1 January 2004), an applicant would not receive any examination unless a Demand for International Preliminary Examination was filed and the application was processed under Chapter II of the PCT. For cases filed after this date, an applicant would receive a written opinion of the search examiner with the International Search Report.

²¹ Patent Cooperation Treaty, *PCT International Search and Examination Guidelines*, World Intellectual Property Organization, 1 July 2014, Chapter 14, §14.04, ("*Guidelines*"), p.122 (**R-041**).

applicability will be self-evident and that an explicit description will not be required.²² I agree with Mr. Erstling that this is true in most cases. But it is not true in all cases.

32. If it is not obvious from the disclosure that the invention has utility, Chapter 14 of the Guidelines requires the IPEA examiner to look to the claimed invention and the Guidelines to determine whether the claimed invention has utility.²³ The Appendix prescribes a three-pronged test for this purpose of the IPEA advisory opinion. The examiner must determine if the claimed invention has utility that is (a) specific; (b) substantial; and (c) credible.²⁴ All three of these requirements must be met for an examiner to render a positive opinion on utility. If an IA fails to satisfy this “credible utility” element, the IPEA examiner will render a negative opinion with respect to the utility criterion.

33. For example, the IPEA examiner may need to revert to the three-pronged test when an IA claims a selection invention, singling out specific members of a known generic group and asserting the selected species have unexpected, higher efficacy than other members of the genus and this discovery advances the state of the art sufficiently to warrant a separate, additional term of exclusivity. This is particularly relevant when the same applicant has already enjoyed patent protection for the selected species (compound) in a granted patent claiming the entire genus. In the absence of evidence in the application at the time of filing clearly showing that the selected species (compound) has superior efficacy compared to other members of the genus, it is highly unlikely a POSITA could review the disclosure and conclude the claims covering the selected species (compounds) actually possess the utility (and the unexpectedly higher efficacy) necessary to justify a second term of exclusivity. In the absence of evidence in the

²² *Guidelines*, Chapter 14, §14.05, p.122 (R-041).

²³ It should be noted that the Appendix has a separate test aimed at ‘industrial applicability’ rather than utility. The wording is the same as TRIPS and NAFTA, in that industrial applicability and utility may be deemed to be synonymous, and yet the Appendix provides different tests for the two. This implies that either term can be used, but that the substantive meaning of the terms differ. *See: Guidelines*, Chapter 14, §14.01, p.122 (R-041)

²⁴ *Guidelines*, Chapter 14, A14.01[1], pp.122-123 (R-041).

application, a POSITA and the IPEA examiner would only have the publicly available information (such as the patent disclosure covering the genus) on which to rely. In such circumstances, the IPEA examiner or a POSITA may well have to revert to the three-pronged test for utility, forming a judgment based on the matter disclosed in the application at the time of filing to determine if the claimed invention has the requisite utility.²⁵

34. Mr. Erstling alleges that all that is required in the description is an explicit indication of utility. However, the fact that the Guidelines themselves mandate that examiners must look to whether a claimed invention has “credible utility” contradicts Mr. Erstling’s assertion. The Guidelines establish that the drafters of the PCT envisioned that more than an explicit indication of utility will be required in some cases.

B. The Training Materials allow flexibility

35. If Mr. Erstling is correct in his assertion that Article 27(1) restricts the ability of States to implement their substantive criteria for patentability through its “form and contents” requirement, one would expect it to be highlighted in the training materials generated by WIPO.²⁶ One of the premier WIPO publications on the PCT is the *PCT Applicant’s Guide*, which is publicly available on the WIPO website. Looking at the Applicant’s Guide we find only one passing reference:

4.011. There is a prescribed form for the international application. This form must be accepted by all designated Offices for the purposes of the national phase, so that there is no need to comply with a great variety of widely differing formal requirements in the many countries in which protection may be sought.²⁷

²⁵ The test for industrial applicability similarly states that the criteria must be met as of the date of filing. See, for example, the Appendix to Chapter 14 of the Guidelines, A-14.01(c), where the examiner is directed to refer to the information in the disclosure when determining credible utility.

²⁶ From 2006 through 2015 I was a consultant to WIPO charged with teaching the PCT in seminars throughout the US, and also operating a “help desk,” answering questions regarding the PCT and its use (through 2014).

²⁷ *PCT Applicant’s Guide (International Phase)*, World Intellectual Property Organization (WIPO) International Bureau (July 24, 2014), (“*PCT Applicant’s Guide*”), p. 6, 4.011 (emphasis added) (**R-042**)

36. This is the only mention in the materials routinely relied upon by PCT patent applicants, as well as by WIPO officials and its consultants in teaching and training, with respect to the formalities that a PCT applicant must comply with. This supports the conclusion that the phrase “form and contents” as included in Article 27(1) relates only to formalities, the categories of information which should be disclosed, the order and format of the IA, and so on. Mr. Erstling has overstated the importance of standardization of “form and contents”. It does not relate to the requirements of proving that substantive patent law have been met in an application.

37. The *PCT Applicant’s Guide* also warns applicants of the need to draft the application with requirements of the most stringent country in mind:

5.095. The details required for the disclosure of the invention so that it can be carried out by a person skilled in the art depend on the practice of the national Offices. It is therefore recommended that due account be taken of national practice (for instance in Japan and the United States of America) when the description is drafted. The need to amend the description during the national phase (see paragraph 5.111 below) may thus be avoided.²⁸

38. As noted in my first report, Mr. Helfgott, who co-authored the *Practitioner’s Guide to the PCT* with Mr. Erstling and myself, makes the same recommendation. He advised:

In order to be sure that your PCT application will be a viable application in foreign countries, care must be given to the various laws in foreign countries that may be different from those in the United States. In many cases the patent laws of many countries have been harmonized, but there are still differences, and these must be considered.²⁹

39. As I stated in my first report, international applications must be drafted with a view to meeting the most stringent national requirements. One of the drawbacks to a “one size fits all” disclosure is that the applicant must ensure that the disclosure meets

²⁸ *PCT Applicant’s Guide*, p. 29 (R-042).

²⁹ Jay Erstling, Samson Helfgott and T. David Reed, *The Practitioner’s Guide to the PCT*, Chicago, Illinois: American Bar Association, Section of Intellectual Property Law, (2013), P. 200 (emphasis added) (R-043)

the most stringent requirements across the Contracting States. Failure to do so can result in loss of rights. In teaching the PCT, I always made sure the attendees were aware of this need. An applicant cannot assume the disclosure of the priority application will meet the requirements in all foreign countries. When the priority disclosure does not, the applicant should utilize the single rewrite to redraft the disclosure to include all information needed across the globe.

40. This advice is particularly relevant to selection inventions. In order to justify an additional period of exclusivity, the unexpected increase in efficacy of the selected species in comparison to the genus must be demonstrated to show the claimed invention has the requisite utility to justify an additional period of exclusivity.

C. Other PCT Contracting States act as if they understand that they have flexibility under the PCT

41. The practice of PCT Contracting States indicates that they do not feel restricted by Article 27 and Rule 5, as Mr. Erstling asserts, in their ability to prescribe and implement their substantive conditions of patentability.

42. For example, in my view, the instant situation is parallel to the example in my first report regarding the sufficiency of disclosure in relation to the scope of the claims in Japan. In Japan, the applicant may be required to cancel or reduce the scope of the claims during prosecution where there are insufficient examples in the disclosure to support the scope of the claim as originally drafted. In Japan, failure to provide examples in the disclosure is a defect that cannot be corrected after filing - the examples must be in the application at the time of filing. Where an applicant is found to have provided insufficient examples, the applicant's only recourse is either (i) to reduce the scope of the claims to conform to the scope of the examples originally filed; or (ii) cancel the claims for which there is insufficient support. The Japan example clearly indicates that a patent application which may be acceptable in one or more PCT countries may be judged inadequate in others. In both cases the consequences for the

applicant is loss of patent rights for failure to conform with substantive patentability requirements in domestic systems.

V. CONCLUSION

43. After carefully considering the arguments and statements in Mr. Erstling's second expert report, and a fulsome review of the PCT and its related documents, I conclude that the term "form and contents" as used in Article 27(1) relates solely to formal and not substantive matters. During all my years of practice, and in all the PCT applications that I have filed, I have never understood Article 27(1), Rule 5.1(a), or anything else in the PCT to preclude Canada, or any other Contracting State, from requiring that an applicant disclose the basis of a sound prediction of utility in the IA at the time of filing. Based on my subjective experience as a U.S. patent agent with almost two decades of PCT experience, I am of the view that Canada's utility requirement is firmly in compliance with the PCT.

Signed at Cincinnati, OH, US on: 7 December 2015

[signed]

T. David Reed